MEDICARE'S MANAGEMENT: IS HCFA'S COMPLEXITY THREATENING PATIENT ACCESS TO QUALITY CARE?

HEARING

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

JUNE 27, 2000

Serial No. 106–125

Printed for the use of the Committee on Commerce

U.S. GOVERNMENT PRINTING OFFICE
65–913CC WASHINGTON : 2000

COMMITTEE ON COMMERCE

TOM BLILEY, Virginia, *Chairman*

W.J. "BILLY" TAUZIN, Louisiana
MICHAEL G. OXLEY, Ohio
MICHAEL BILIRAKIS, Florida
JOE BARTON, Texas
FRED UPTON, Michigan
CLIFF STEARNS, Florida
PAUL E. GILLMOR, Ohio
Vice Chairman
JAMES C. GREENWOOD, Pennsylvania
CHRISTOPHER COX, California
NATHAN DEAL, Georgia
STEVE LARGENT, Oklahoma
RICHARD BURR, North Carolina
BRIAN P. BILBRAY, California
ED WHITFIELD, Kentucky
GREG GANSKE, Iowa
CHARLIE NORWOOD, Georgia
TOM A. COBURN, Oklahoma
RICK LAZIO, New York
BARBARA CUBIN, Wyoming
JAMES E. ROGAN, California
JOHN SHIMKUS, Illinois
HEATHER WILSON, New Mexico
JOHN B. SHADEGG, Arizona
CHARLES W. "CHIP" PICKERING, Mississippi
VITO FOSSELLA, New York
ROY BLUNT, Missouri
ED BRYANT, Tennessee
ROBERT L. EHRLICH, Jr., Maryland

JOHN D. DINGELL, Michigan
HENRY A. WAXMAN, California
EDWARD J. MARKEY, Massachusetts
RALPH M. HALL, Texas
RICK BOUCHER, Virginia
EDOLPHUS TOWNS, New York
FRANK PALLONE, Jr., New Jersey
SHERROD BROWN, Ohio
BART GORDON, Tennessee
PETER DEUTSCH, Florida
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
RON KLINK, Pennsylvania
BART STUPAK, Michigan
ELIOT L. ENGEL, New York
TOM SAWYER, Ohio
ALBERT R. WYNN, Maryland
GENE GREEN, Texas
KAREN MCCARTHY, Missouri
TED STRICKLAND, Ohio
DIANA DEGETTE, Colorado
THOMAS M. BARRETT, Wisconsin
BILL LUTHER, Minnesota
LOIS CAPPS, California

JAMES E. DERDERIAN, *Chief of Staff*
JAMES D. BARNETTE, *General Counsel*
REID P.F. STUNTZ, *Minority Staff Director and Chief Counsel*

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

MICHAEL BILIRAKIS, Florida, *Chairman*

FRED UPTON, Michigan
CLIFF STEARNS, Florida
JAMES C. GREENWOOD, Pennsylvania
NATHAN DEAL, Georgia
RICHARD BURR, North Carolina
BRIAN P. BILBRAY, California
ED WHITFIELD, Kentucky
GREG GANSKE, Iowa
CHARLIE NORWOOD, Georgia
TOM A. COBURN, Oklahoma
Vice Chairman
RICK LAZIO, New York
BARBARA CUBIN, Wyoming
JOHN B. SHADEGG, Arizona
CHARLES W. "CHIP" PICKERING, Mississippi
ED BRYANT, Tennessee
TOM BLILEY, Virginia,
(Ex Officio)

SHERROD BROWN, Ohio
HENRY A. WAXMAN, California
FRANK PALLONE, Jr., New Jersey
PETER DEUTSCH, Florida
BART STUPAK, Michigan
GENE GREEN, Texas
TED STRICKLAND, Ohio
DIANA DEGETTE, Colorado
THOMAS M. BARRETT, Wisconsin
LOIS CAPPS, California
RALPH M. HALL, Texas
EDOLPHUS TOWNS, New York
ANNA G. ESHOO, California
JOHN D. DINGELL, Michigan,
(Ex Officio)

CONTENTS

	Page
Testimony of:	
Coble, Yank, Board of Directors, American Medical Association	80
Fleming, Dave, Group Senior Vice President, Diagnostic Products and Genetics, Genzyme Corporation on behalf of AdvaMed	65
Gottlich, Vicki, Center for Medicare Advocacy and the National Academy of Elder Law Attorneys	89
Hash, Michael, Deputy Administrator, Health Care Financing Administration	12
Mangano, Michael F., Principal Deputy Inspector General, Office of Inspector General, Department of Health and Human Services	73
Waller, Robert R., Chairman, Healthcare Leadership Council	58
Material submitted for the record by:	
American Association of Orthopaedic Surgeons, prepared statement of	107
American Psychiatric Association, prepared statement of	110
Hash, Michael, Deputy Administrator, Health Care Financing Administration, responses for the record	120
Mangano, Michael F., Principal Deputy Inspector General, Office of Inspector General, Department of Health and Human Services:	
Letter dated July 6, 2000, to Hon. Tom Coburn, enclosing response for the record	116
Letter dated July 6, 2000, to Hon. Charles Norwood, enclosing response for the record	117
Waller, Robert R., Chairman, Healthcare Leadership Council, additional comments for the record	114

MEDICARE'S MANAGEMENT: IS HCFA'S COMPLEXITY THREATENING PATIENT ACCESS TO QUALITY CARE?

TUESDAY, JUNE 27, 2000

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:07 a.m. in room 2322, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Upton, Stearns, Greenwood, Burr, Whitfield, Ganske, Norwood, Coburn, Bryant, Brown, Strickland, Barrett, Capps, and Eshoo.

Staff present: Tom Giles, majority counsel, Carrie Gavora, majority professional staff, Kristi Gillis, legislative clerk, Bridgett Taylor, minority professional staff, and Amy Droskoski, minority professional staff.

Mr. BILIRAKIS. I am pleased to convene this hearing on the management of the Medicare Program by the Health Care Financing Administration.

As this Congress has considered proposals to expand coverage of prescription drugs under Medicare, I have been struck by one of the common themes throughout several of the proposals.

On both sides of the aisle there seems to be a pervasive belief that any additional Medicare benefit, especially one as important and difficult as prescription drug coverage, should not be administered by HCFA.

This hearing is especially significant because any effort to reform Medicare must include a careful review of the agency that administers the program.

I do not intend to bash HCFA; rather, I want to conduct a thorough examination of the Health Care Financing Administration, its regulations, policies and interactions with stakeholders as well as the impact with Congressional mandates.

In the last Congress this subcommittee took a hard look at the Food and Drug Administration and crafted legislation to make that agency more consumer-friendly, more user-friendly, and more patient-friendly.

I believe that the time has come to begin a similar review of HCFA as part of a broader effort to modernize both the agency and the Medicare Program.

Beginning with this hearing, it is my plan to launch a serious, responsible, and bipartisan HCFA reform effort.

Today we will hear from the medical device industry and health care providers, as well as Mr. Mike Hash, the Deputy Administrator of HCFA. I am hopeful that we will begin to understand some of HCFA's delays in implementing Federal law, including the hospital outpatient prospective payment system rule and the long-term care hospital prospective payment system rule.

This Congress continues to debate managed care reform and prescription drug coverage. There is also considerable interest and speculation regarding the budget surplus and further refinements to the 1997 Balanced Budget Act.

My staff is currently working to identify additional changes necessary to remedy unintended consequences of the Balanced Budget Act and to restore essential funding.

In addition to HCFA reform, we welcome the input of the larger health care community on these issues. However, I hope we can keep this hearing focused on the critical issue before us and that is HCFA modernization and reform.

I look forward to hearing from the agency and its stakeholders today. We must continue to work together to improve HCFA until it is truly consumer-friendly, user-friendly, and patient-friendly.

I would say at the outset that the opening statement of all Members of the subcommittee will hereby be made a part of the record and I will now yield to Mr. Brown for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman. I would like to welcome Mike Hash and our other distinguished witnesses. Thank you for joining us.

Most of us actually on this side of the aisle, many in this Congress do believe that prescription drug should in fact be administrated by HCFA.

I don't question, Mr. Chairman, the value of this hearing. If there are ways HCFA can improve, can streamline its operations, as I am sure there are, we should encourage those changes. Coverage decisions should be made on a fair and timely basis.

If there is any question as to whether those standards are being met, we should hear about it; similarly, with the efforts of Congress and the administration, to rout out fraud and abuse. There is a fine, but important, line between aggressive and abusive scrutiny of Medicare providers.

However, if the goal truly is to do what is best for Medicare beneficiaries and not to bash HCFA, then I would like to suggest the following:

First, HCFA does not operate in a vacuum. If there are problems in the administration Medicare Program, we in Congress share the blame. The executive branch shares the blame and Medicare providers share the blame.

We starve HCFA and at the same time multiply its responsibilities. We legislate payment policy. We legislate restrictions on Medicare's use of cost containment mechanisms. We even legislate the specifics of complex payment systems and then we complain that HCFA just isn't flexible enough. We fault HCFA for red tape that if we took the time to trace it back, probably derives from

pressure that we on this subcommittee and we on this full committee and we in this Congress placed on the agency.

Medicare providers lobby us to restrict HCFA's authority, to dictate their every action, and the same providers vilify HCFA for their "by the book" bureaucratic approach.

Last January 14, top health policy experts from across the political and ideological spectrum got together and wrote an open letter to Congress and to the administration. I am not exaggerating the diversity or credentials of this group, Marilyn Moon, Stewart Butler, Gail Walinsky, Robert Helms, Uwa Reinhardt, Robert Reicher, William Roper, a virtual who's who across the ideological spectrum in health policy, all signed their name to this document.

This letter, which I would like to submit for the record, was published in the Journal of Health Affairs. I want to share some of the letter with you, beginning with the first paragraph.

"The signatories to this statement believe that many of the difficulties that threaten to cripple HCFA stem from an unwillingness of both Congress and the Executive to provide the agency the resources and the administrative flexibility to carry out this mammoth assignment.

"This is not a partisan issue because both Democrats and Republicans are culpable for their failure to equip HCFA with the human and financial resources it needs. They continue no private health insurer after subtracting its marketing costs and profit, would ever attempt to manage such large and complex insurance programs with so small an administrative budget."

They are referring to the fact that HCFA's administrative expenses represent 1 percent of the Medicare Trust Fund and only 2 percent of Part B spending. It leads me to my second point, Mr. Chairman.

If you think private insurers can do a better job than HCFA, and in part that is what the prescription drug debate is all about, ask yourself the following questions:

One, when you hear complaints about Medicare, how often are the complaints actually directed at the private contractors that administer Medicare benefits?

Two, can you name a private insurer that markets indiscriminately to the healthy and the sick, that willingly covers pre-existing conditions, that wouldn't reduce benefits, that wouldn't drop enrollees if that meant making more money?

Four, how much administrative costs does a private insurer typically absorb or typically take?

Five, why do an overwhelming majority of Americans believe we need a patient's bill of rights to ensure that private insurance plans deliver on their promises?

Six, why are 44 million individuals uninsured?

Seven, why when we receive phone calls and letters from providers complaining about red tape, questionable coverage decisions and slow claims turnaround, is it so often the private insurance industry these providers are referring to.

If there are actions we can take, if there are changes in what we do and what HCFA does that can improve this program's operations, let's make those changes.

But I hope, Mr. Chairman, this hearing doesn't just become a vehicle for some of my colleagues to promote Medicare privatization or an excuse to deflect responsibility we all share by making this government agency a scapegoat.

Taking this hearing in either direction would be a regrettable waste of time.

Mr. BILIRAKIS. I thank the gentleman. Before I recognize the other members of the subcommittee, I would ask unanimous consent that a June 12, 2000 letter signed by better than 60 Members of the House, a very bipartisan letter, a very large number of Members of the other party are signatories to that letter requesting this hearing. I request it be made a part of this record.

Without objection, that will be the case. The letter says: "We are writing to request that you consider holding oversight hearings of HCFA and its carriers. We are concerned at the complexity of the program and the chevron of regulations that health care providers must now provide are serving as an impediment to quality health care services for Medicare beneficiaries, et cetera."

Then the last paragraph, "Our overwhelming goal is to create a stronger and more effective HCFA that will be able to meet the challenging needs of the growing elderly population."

I would suggest to my ranking member, who is my very good friend, that that is the goal of this hearing, and not, as I said at the outset, to bash HCFA. The paragraph goes on:

"If HCFA is not able to adequately meet these needs we are worried that access to quality health are services for our most vulnerable population will continue to get worse.

"In the interest of Medicare beneficiaries and for the physicians who participate in the program, we urge that your committee takes prompt action."

[The letter follows:]

CONGRESS OF THE UNITED STATES
WASHINGTON, DC
June 12, 2000

The Honorable THOMAS BLILEY
Chairman
Committee on Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable MICHAEL BILIRAKIS
Chairman
Committee on Commerce
Subcommittee on Health and Environment
2125 Rayburn House Office Building
Washington, D.C. 20515

DEAR MR. CHAIRMEN: We are writing to request that you consider holding oversight hearings of the Health Care Financing Administration and its carriers. We are concerned that the complexity of the program and the sheer volume of regulations that health care providers must now comply are serving as an impediment to quality health care services for Medicare beneficiaries.

We believe that every effort should be made to eliminate fraudulent activity in every Federal health care program. We also are concerned that Medicare's complex laws and unclear regulatory guidance have created an environment where honest providers fear that simple mistakes will trigger punitive fraud investigations. Many honest physicians believe that the risks are becoming too great and are not willing to accept new Medicare patients.

The successful management and operation of HCFA and its carriers are critical to Medicare beneficiaries and health care providers. Hearings could identify the short-term challenges and the long-term goals of the Health Care Financing Administration. These topics could include:

- Are current HCFA initiatives effective at eliminating truly fraudulent activity?
- Have HCFA's initiatives, such as "Who Pays, You Pay" program, rooting out fraud, and how much detrimental effect have these initiatives had on the physician-patient relationship?
- Does the emphasis on documentation (quantitative concerns), have an adverse effect on quality (qualitative) patient care?
- Are inadvertent billing errors and judgment decisions being confused with intentional acts to defraud the Medicare program; what has been the effect of random post payment audits on honest medical practices?
- Are there more effective governmental approaches to eliminating fraud and abuse that do not impose such a "hassle factor" on honest physicians?

Our overwhelming goal is to create a stronger and more effective HCFA that will be able to meet the challenging needs of the growing elderly population. If HCFA is not able to adequately meet these needs, we are worried that access to quality health care services for our most vulnerable population will continue to get worse. In the interests of Medicare beneficiaries and for the physicians who participate in the program, we urge that your Committees take prompt action.

Sincerely,

Signatures on Commerce Committee letter: Donald A. Manzullo, Collin Peterson, Spencer Bachus, Jim McGovern, John E. Sweeney, Richard H. Baker, Mark Souder, Van Hilleary, Julia Carson, Shelley Berkley, Robert Stump, Lloyd Doggett, Darlene Hooley, Mark Green, Lindsey Graham, David Phelps, David McIntosh, John Baldacci, Bob Ney, Jack Kingston, Ronnie Shows, John Shadegg, Edolphus Towns, Martin Frost, Terry Everett, Tom Cambell, Floyd Spence, Elton Gallegly, Johnny Isakson, James Sensenbrenner, Jr., Jerry Moran, James A. Gibbons, Zoe Lofgren, Jim Ryun, Robert A. Brady, Ron Paul, Mark Foley, Jo Ann Emerson, Louise M. Slaughter, Rodney Frelinghuysen, Dave Weldon, Roger F. Wicker, Michael E. Capuano, Earl Blumenauer, Sanford D. Bishop, Jr., George R. Nethercutt, Jr., Lynn Rivers, Saxby Chambliss, Larry Combest, Judy Biggert, Pat Toomey, Frank D. Lucas, Patsy T. Mink, Sherwood Boehlert, Nick Rahall, John M. McHugh, David Vitter, Wally Herger, Doug Bereuter, Bill Barrett, James E. Clybrn, and Sue Kelly.

Mr. BILIRAKIS. That having been said, the Chair now recognizes Dr. Ganske for an opening statement.

Mr. GANSKE. Thank you, Mr. Chairman. I hope that the committee learns something to day about how the Health Care Financing Administration can work more efficiently and to the benefit of the consumers, the beneficiaries, as well as providers that provide the care.

All Congressman get phone calls and letters into their office about bureaucratic snafus with all government agencies, but HCFA is one of those that we receive, and as a past medical practitioner, I can say that I have had some questions that have gone into HCFA, too. But I would like to echo Mr. Brown's sentiments and that is that a lot of the questions that Congressman and Congresswoman get are generated from laws that Congress passes and then requires HCFA to implement.

In 1997, BBA was a pretty complicated bill. It required HCFA to break ground on a lot of things like prospective payment systems which are not easy to implement, which have never been done before.

When you starve an agency, I think you need to step back a little bit before you criticize whether the agency can get its job done.

So, I have been a supporter of increased funding for the Health Care Financing Administration for several years, primarily because I have voted for some of the laws that we have passed that require

HCFA to do an increased job. Let me give you an example. For several years, Congress has been interested in HCFA clamping down on fraud and abuse. That requires a certain amount of manpower.

On the other hand, I have heard questions and comments about whether they have been over-zealous in that report, which brings up the never-ending conflict between how Congress writes laws. Do you write laws that are so proscriptive that the administrators have no leeway, but then become very, very complicated or do you write laws that allow some flexibility, that allow administrators to use some common sense?

However, because some of their decisions may not be liked by certain providers or groups, they then come back to Congress and say, "You need to tighten up the proscriptions on how this is done."

It is a never-ending balance. It is not just with this bill. It is with all the legislation that Congress does. It is that fine line of writing legislation that accomplishes what it wants to do, but at the same time allows some common sense.

There was a very good book written on this a few years ago on how to do common sense legislation and some of the problems that Congress has had with it.

Finally, I want to say that this hearing should not be used as a way to promote one prescription drug plan over another.

I went to the rules committee yesterday and asked for a substitute on my bill which I introduced, H.R. 4743, which follows some of the lines that the Chairman has done with his bill, which would basically allow poor Medicare beneficiaries who are not dual eligible to access State Medicare drug grants up to 175 percent of poverty.

That solution would not increase the HCFA bureaucracy, other than the fact that those Medicare beneficiaries would be able to access drug programs that are already run by the States and where the States have already achieved discounts with the pharmaceuticals.

So, my proposal would not increase the bureaucracy or set up a separate bureaucracy. There are alternatives in this. But I think that this hearing should not be utilized as a way to promote one plan or another, to bash HCFA, to say that now we need to have a separate agency running part of what I think should be a comprehensive medical package of benefits.

So, with that, Mr. Chairman, I will yield back.

Mr. BILIRAKIS. I thank the gentleman. As you can see, we are not here to bash HCFA.

I recognize Ms. Capps for an opening statement.

Ms. CAPPS. Thank you, Mr. Chairman. I appreciate that you have decided to hold this most important hearing today on, as we have discussed, the relationship between Health Care Financing Administration's policies and the quality of care.

Medicare is a sacred program to many of today's seniors. They count on Medicare for their health care and I believe we all agree they should be able to count on being able to do so in the future.

In administering Medicare, HCFA is involved in a delicate balancing act. While we don't want to compromise patient care or medical advances with excessive regulation, we also want to make

sure that the agency preserves a high level of program integrity and works to reduce fraud, waste and abuse.

That being said, I believe there are many areas that need improvement when it comes to Medicare's management. I am concerned about patient access to Medicare technologies.

I have heard repeatedly from device manufacturers who are unhappy with the HCFA coding and payment system. These systems make it difficult for beneficiaries to gain access to innovative technologies and procedures, even when Medicare covers these therapies.

The manufacturer's primary concern is that technologies are reaching Medicare patients much too slowly because of delays and complexities related to these processes.

In my own district, facilities such as Medtronics, PS Medical and Galleta are feeling the impact of this. Device manufacturers have also expressed specific concern over HCFA's rationale behind the new perspective payment system and the implementation of the transitional pass-through payments for medical devices.

These concerns have led me to cosponsor HR. 4395 authored by my colleagues Karen Thurman and Jim Ramstad. This legislation requires HCFA to adjust and update more frequently Medicare's payment and coding systems so that Medicare beneficiaries can receive timely access to medical technologies.

H.R. 4395 will help shorten the time it takes for medical products and therapies to reach nearly 40 million Medicare patients today.

I cite this as one example of the way we need to work together and not in an adversarial relationship, but in a cooperative way to increase access, keep competition sharp, but also just be aware constantly of the difference in health and in many instances life and death the these decisions and these processes make with patients who are so dependent on the regulations that govern this agency.

There are so many exciting new advances in medical device technology. This is new. When Medicare began I don't imagine there were more than a handful of technologies, which fit into this category. Now, they are springing up around the country.

It is incredibly important that we stay sharp and able to deal with them as they come along. Many companies spend years navigating the rigorous FDA approval process for these often life-saving technologies. Then they are subjected to long and often unnecessary waiting periods by HCFA for administrative reasons, which to every patient and to every provider must seem terribly wasteful and pointless.

Sadly, after manufacturers receive HCFA's approval for coverage, their products are sometimes out of date by that time. This type of over-regulation hurts the manufacturers. But in the end it really hurts patients.

I believe that Congress must work closely with HCFA to create an environment in which medical device manufacturers and entrepreneurs can bring safe and effective medical devices to the public with deliberate speed and timeliness.

HCFA has to keep pace with this innovation. To do otherwise is to short change patients across this country. I believe in Medicare. And I believe this institution also shares that conviction.

We must therefore commit ourselves to improving the administration of the program. We must work with you in HCFA to help in this balancing act, to preserve program integrity while encouraging innovation.

I yield back the balance of my time.

Mr. BILIRAKIS. I thank the gentlelady.

I recognize Dr. Norwood for an opening statement.

Mr. NORWOOD. Thank you, Mr. Chairman. I have a very extensive, lengthy statement that I would like to submit for the record.

Mr. BILIRAKIS. Without objection.

Mr. NORWOOD. I will just make a brief comment.

Mr. BILIRAKIS. Without objection, that will be the case, too, I trust.

Mr. NORWOOD. The brief part, right.

Well, first I want to thank you. I think this is a very important, it is always timely with HCFA to have this type of hearing and I do believe all of us really think authority you are correct in what this is about, this change.

You can say it any way you want to. You can call it modernization. You can call it reform, but what we are really all screaming for is change in a system today that is not working well.

I don't think we can find many people who would disagree with that. Now, I don't care to blame that on the administrators particularly or the managers at HCFA, although they share some of the blame. I think Congress shares probably more blame and certainly the Executive.

But the bottom line is that we have an agency that is not doing well in terms of the patients of this country and the providers of care. We need to agree on both sides of the aisle that change doesn't have to be bad. It can be good. It can be innovative. That is really all we wanted to do.

The last Georgian that spoke out on this subject was demagogued for a year. I cannot tell you how many television commercials. Because he would dare say that HCFA should wither on the vine. What that really means is that was an agency that he thought really needed to be overhauled or indeed changed totally if necessary so that it works for the patients of America.

I want to thank you first, but encourage you, too, Mike. I don't think we can do this too often because we have to get to a point where both sides of the aisle will agree that legislative change has to be in the making before we are ever going to have this largest agency in the world improve.

In my office I am proud to report that the IRS is still No. 1 with complaints. But HCFA if close behind. There is no reason that has to happen. I blame a lot of that on the Congress of the United States.

With, Mr. Chairman, I thank you for the opportunity.

Mr. BILIRAKIS. I thank the gentleman. You have sort of paraphrased, in a way, much of what Dr. Ganske has said.

I think the biggest concern that I have is that I would like to think that both sides of the aisle are interested in doing what is right here.

But I have oftentimes in the past asked Mr. Hash and other members of HCFA why they don't make suggestions to us?

Why don't they approach us and tell us, hey, the language in this legislation is restrictive and it keeps us from doing the job that we feel that we want to do as well as we need to do it.

Those are the concerns that I oftentimes have, just the lack of needed communication.

Mr. Whitfield.

Mr. WHITFIELD. Mr. Chairman, thank you and I also am pleased that you are having this hearing. I think every Member of Congress spends a lot of time with physicians, hospital administrators, and other providers relating to health care because it certainly is one of the most complex problems we have facing our society today.

Yesterday I had an opportunity to meet with a board, a nonprofit board connected with a particular church that owns seven hospitals and they echoed the concerns by many health providers that I see and that is that the health care system is so micro-managed today that people really feel like they are frequently tied up in knots in trying to abide by various regulations.

I agree with others on this committee who said, you know, we can't run around blaming anybody for this, but I think we have to recognize that there are some genuine concerns out there about whether or not HCFA is unnecessarily interfering in the delivery of health care.

I am sure that nobody has an answer to that. I was looking at some of the testimony and, for example, there is a seven-page guideline as an example describing the examination and documentation requirements for billing under CPT Code 9215, one of only approximately 10,000 CPT codes.

Then I know physicians, for example, feel like that their Practicing Physicians Advisory Council has not been consulted enough, has not worked on a regular basis with HCFA in trying to deal with just some practical problems that they have.

So, I am delighted we are having this hearing. I think it is a very complex subject. Hopefully, we can come up with some information here that may benefit everyone.

So, thank you very much.

Mr. BILIRAKIS. I thank the gentleman. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. Any statement I have I will put in the record. I do want to welcome our good friend, Mike Hash, who is almost a member of this subcommittee, I think, as well as the very distinguished members of the second panel. Thank you.

Mr. BILIRAKIS. I thank the gentleman.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for holding today's hearing on HCFA's management of the Medicare program. As we seek to further modernize the Medicare program, I want us to give serious consideration to whether or not the current system—HCFA's delegating claims payment and fraud and abuse detection to insurance carriers—is working well. Based on my experiences over the years with health care providers and beneficiaries and on the hearing that I held in the Oversight and Investigations Subcommittee on Medicare's management of the carriers, I have every reason to think that this system is not working well for beneficiaries, for providers, and for the taxpaying public.

Let me give you just one example of what I see and experience all to often as I work with my beneficiaries and health care providers. Nearly a month ago, a physician's office manager in my district called my office to see if we could help her and the doctor to figure out what was happening at the carrier. It seemed that they had been receiving scores of requests for additional information about claims that they had submitted electronically. When they called the carrier, they were told that this was a "pre-payment audit" that HCFA had directed the carriers to undertake. When they asked how long the claims would remain pending, the carrier could give them no estimate. When they asked if interest would be paid on claims held beyond a certain period, the carrier told them that HCFA directed them to treat these claims as if they were in a claim category on which interest is not paid. When my constituents checked with the regional HCFA office, that office denied any knowledge of what was going on at the carrier.

The physician now has nearly 40 percent of his Medicare claims being held by the carrier. And despite my staff's and my effort to get a straight answer from Medicare about what is going on here, we have yet to get a complete response—after over a month of prodding.

If my staff person—who has nearly 20 years of dealing with Medicare issues—is having problems of this nature, what about busy doctors and confused beneficiaries? I wish this were a rare situation. It is not. It is in my experience typical of the lack of clear communication between HCFA and its carriers. And it is totally frustrating and maddening for everyone.

Further, as you know, Mr. Chairman, last summer I held an Oversight and Investigations hearing on HFCA's management of its carriers. What we learned in the investigation leading up to the hearing and at the hearing itself was very troubling. Too many carriers, which are supposed to be the first line of defense against Medicare fraud and abuse, were themselves defrauding Medicare.

Again, thank you for holding today's hearing. We've got to get to the bottom of these problems.

PREPARED STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Thank you Chairman Bililrakis for holding important hearing. The purpose of this hearing is to determine whether or not Medicare patients have access to the newest technologies available in the market place. Or, does HCFA's bureaucracy limit our nation's seniors access to medical treatments available to all other Americans. Is HCFA a bureaucratic nightmare that needs to be streamlined and brought into the 21st century? Without sounding like I'm piling on and being too critical, I think the answer has to be yes.

With the many technological changes that have occurred since the program began and the need to keep pace with future advances that will be made, it is necessary that the program be overhauled completely. We need to help seniors gain access to affordable prescriptions and the newest technology available through insurance coverage and the truly effective price competition of an active marketplace. That is why I support the idea of using the Federal Employees Health Benefits Program (FEHBP) as a model. This would ensure that seniors would have access to newer drugs and devices because they would choose the plan they want. In fact, this type of approach would provide Medicare beneficiaries the same options that most federal employees, including the President and Members of Congress have. That is why I feel so strongly about the need to enact the proposal that was developed based on the recommendations of the bipartisan commission. That proposal is S. 1895, the Breaux-Frist bill which would restructure Medicare, using the Federal Employees Health Benefits Program (FEHBP) as a model. This would ensure that seniors would have access to newer drugs and devices because they would choose the plan they want. These plans that do not limit the newest devices and drugs to its beneficiaries and neither should Medicare.

One need look no further than a recent notice that was published by HCFA entitled: "Process to Identify and Obtain Codes for Items Potentially Eligible for Payment as New Technologies or Transitional Pass-Throughs Under the Outpatient Prospective Payment System. This is a good example of how cumbersome the process is and continues to be when new technologies become available and need to be added to their list. In order to have a new technology added to HCFA's list you must apply for a special code. The application process can take up to two years provided the paperwork was sent in by April 1, 2000. It is absolutely ridiculous that in order to bring a new device to Medicare patients that the administrative and procedural

requirements could delay its availability by as much as four or five years. That's not acceptable.

Mr. Chairman, how can anyone be expected to know whether or not correct procedures are being followed—there 100,000 pages of HCFA regulations relating to the Medicare program. Physicians are asked to do the impossible. Unless they follow certain rules and regulations they are liable to be accused of fraudulent behavior. Of course, since what is covered and not covered is decided by HCFA and not the physician, the physician is placed in a compromising position. For instance, if a physician believes that a patient should have a screening evaluation, the physician must state that he thinks a patient has a certain underlying problem. This is the only way a routine screening evaluation with a physical examination and preoperative screening test can be carried out. Why don't we allow physicians to make such decisions without having to go through such a maze of bureaucratic red tape?

HCFA is a bureaucracy dictating how physicians should practice medicine, a bureaucracy that prevents Medicare recipients from having access to the newest medical technology, and a bureaucracy that runs our seniors health care program through a maze of paperwork, codes, rules, regulations, etc., etc.

The answer to the problems that are experienced with anyone using this program is clear. We need a major overhaul of the entire program. Thank you, Mr. Chairman.

PREPARED STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WYOMING

Often times, it is very difficult to realize the true impact of issues and legislation on our local communities.

The chain that extends from the federal government to the states is very long indeed, and each link represents some form of red-tape or another.

HCFA, for example, is this huge entity that is very far removed from the people it serves.

I can't tell you how many times my constituents have come to me with questions about their Medicare benefits because they can find no one at HCFA who will answer their questions. That just isn't right.

I know all too well the problems that physicians are having when it comes to Medicare.

Before I came to Congress, I spent years working with my husband in his medical practice and I know first-hand how difficult it is to deal with 1000 pages of Medicare regulations, and the endless confusion that goes along with the coding procedures.

So much time is being consumed by administrative red-tape that medical practices are having difficultly delivering the care they should. And over the years, it has only gotten worse.

And that's why it is so important for us as Members of Congress to get out there and speak with our constituents and learn first-hand what it is they feel and experience, especially when it comes to health care.

I wonder, however, if HCFA has bothered to do the same thing??

Today, I hope to get a better understanding of how HCFA develops its regulations because, frankly, it is just not responding to the rapidly changing marketplace as quickly as it should.

That needs to be addressed and I hope we can work toward that end.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

I want to thank the Chairman of the Health and Environment Subcommittee, Mr. Bilirakis for convening this hearing today. In 1997, this Committee improved patient access to drug discoveries by passing the Food and Drug Modernization Act. Today we are examining similar issues within the Health Care Financing Administration.

The issue of Medicare complexity has been a growing concern to Congress. I would like to submit for the record a bipartisan letter I received earlier this month from over 60 Members of Congress. They are concerned, as am I, that HCFA is an impediment to Medicare beneficiaries. I hope today's witnesses, particularly Mr. Hash, can address these concerns.

Medicare is vastly complex. The burden imposed by the over 110,000 pages of laws, regulations, manuals and other program guidance is exceeded only by the penalties for failure to comply with these rules. This complexity has negative impacts.

- It steals doctor's time from their patients and research activities.
- It denies seniors timely access to diagnostic tools and treatments.
- It leads to compliance problems for providers trying to do their best to follow the complex rules, but nonetheless finding themselves on the wrong side of the rules.

The Health Care Financing Administration, the agency which oversees Medicare, is an extraordinary bureaucracy. There are approximately 10,000 codes linked to services that physicians and hospitals must use. HCFA oversees 60 different private insurers or "intermediaries" who process and pay the 900 million claims filed by beneficiaries each year.

HCFA micromanages the Medicare program in excruciating detail. HCFA performs tasks such as collecting copays and deductibles, making coverage decisions, managing contracts with hundreds of private health plans, and checking quality, payment rates and billing compliance.

Today's hearing is particularly timely given the current debate on adding a prescription drug benefit to the Medicare program. Both Democrats and Republicans have introduced separate legislation which would bring the administration of the benefit under an entity other than HCFA. The issue of self-injectable drugs which this subcommittee addressed at a hearing earlier this year, illustrates the potential problem of allowing HCFA to administer an expanded prescription drug benefit.

I am hopeful this hearing will shed light on some of the thinking behind the decisions being made at HCFA. Congress has made many changes to the Medicare, Medicaid and SCHIP programs, as well as changes to the private health insurance market with the enactment of the Health Insurance Portability and Accountability Act, over the past four years. In part, many of these provisions were enacted to reign in the costs of federal programs. However, in no way did Congress ever intend to compromise the quality of care patients in these programs receive.

Mr. BILIRAKIS. Michael, why don't you come forward? We have two panels today. Panel One consists of Mr. Mike Hash. You have already heard his name a number of times this morning. He is the Deputy Administrator of HCFA.

Mr. Hash was a long-time counsel to this subcommittee and we have gotten to know him quite well before and after, if you will.

Michael, you are representing the administration. The clock is at 10 minutes. Please proceed, sir.

STATEMENT OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Mr. HASH. Thank you, Chairman Bilirakis, Congressman Brown and distinguished members of the subcommittee. I want to thank you for inviting us here today to discuss our progress in attempting to streamline Medicare policies and help providers participate in the Medicare Program.

I also want to say I am very much heartened by, and very appreciative of, the remarks that all the Members made in their opening statements about the purpose of this hearing and about their willingness to participate, and continue to participate, in a constructive dialog about how we can strengthen and improve our program.

I take those offers quite seriously and want to continue working with all of you toward the ends that you identified, which we share wholeheartedly.

All of us are interested in minimizing Medicare regulations and maintaining and strengthening the program's efficiency and integrity. I think we all appreciate, as some of you observed in your opening statements, that the challenges that these goals present, which are sometimes conflicting goals, are very serious ones.

Such concerns have been heightened, I think, by the Balanced Budget Act's substantial impact on providers and by our success in fighting waste, fraud, and abuse in the Medicare Program.

We are now taking a number of steps to review our policies for ways that they might be strengthened, streamlined, and simplified. We are also working to more sharply target our program integrity efforts and to make sure that providers have the information they need to do the right thing.

Helping us in these efforts are several steps that we have recently taken. One is something known as our Physicians Regulatory Issues Team, or PRIT, as we call it. Its job is to review, clarify, and simplify rules, and ensure that the concerns of clinicians are heard and addressed in our programs and procedures.

This team is developing an impact analysis initiative to ensure that we explicitly address how our policies affect practicing physicians.

It is also establishing a sentinel practices system to query and monitor a selection of physician practices around the country and to receive ongoing and real time feed back on the real world day-to-day impact of Medicare rules on the practice of medicine.

Another important effort we have under way is the development of simplified evaluation and management guidelines.

One of you in your opening statements referred to the later testimony in which this is referred to. This is an effort designed to make simpler the guidelines for physicians as they make their decisions about coding for the level of visits they provide to Medicare beneficiaries.

We want to make sure that these guidelines are clear, unambiguous, and streamline the documentation that is required to support claims that are submitted for physician services.

We will soon be testing this new evaluation and management guideline approach to get direct physician input on whether they are really better in the real world of physician practice.

We are also revamping the advanced beneficiary notices that providers give to beneficiaries when providing an item or service that Medicare may not cover.

We want plain language, user friendly notices, explaining that a given service or item may not be covered and that the beneficiary may be responsible for paying for the service, so that the beneficiary can ultimately make an informed consumer choice.

We have several other initiatives under way that are addressed in my written testimony. Several of these are designed to focus more sharply on our program integrity efforts.

We realize that, in our efforts to reduce waste, fraud, and abuse in the Medicare Program, we have generated substantial concerns on the part of the provider community.

We know, and we continue to believe, that the majority of providers are honest and conscientious and we have no intention of punishing or pursuing anyone for honest mistakes.

If providers do make billing errors, we want to find these errors, preferably before we make our payments, but there is a world of difference between honest errors and the kind of outright fraud that we have been so successful in fighting.

We do not refer providers to law enforcement for minor or occasional errors. Only the most serious matters are referred to law enforcement agencies. In fact, while some 660,000 physicians receive

Medicare payments each year, we only review 1 percent of physician claims.

In the past 2 years, physicians have accounted for only 52 of the some 500 criminal health care convictions related to fraud at a time when the Department of Justice has achieved an 85 percent conviction rate on fraud cases that it brings to court.

Professor Uwa Reinhardt at Princeton, I think, provided a key perspective on all of this in a recent op ed piece that appeared in the Wall Street Journal. He noted that if those complaining about our regulations were to be brutally frank and honest, they would have to admit that the complexity is often the result of special accommodations for specific circumstances recommended by providers of services to Medicare beneficiaries.

In the end, he says, a compromise must be struck between rules, which are so crude as to tolerate widespread abuse, and rules so finely honed as to become impenetrable.

We want to work with Congress and the health care community to strike the right balance. The past few years have been particularly difficult for providers due to the many BBA changes and our vigorous program integrity efforts.

But now I believe we are turning a corner. We are moving beyond implementation of the BBA.

We are strengthening and expanding our efforts to help honest providers and we are more sharply targeting our fight against fraud, waste, and abuse.

Mr. Chairman, I want to again thank you for holding this hearing and giving us an opportunity to continue a constructive collaboration to improve and strengthen our program.

I look forward to responding to any questions that you and other members of the subcommittee may have.

[The prepared statement of Michael Hash follows:]

PREPARED STATEMENT OF MICHAEL HASH, DEPUTY DIRECTOR, HEALTH CARE FINANCING ADMINISTRATION

Chairman Bilirakis, Congressman Brown, distinguished Subcommittee members, thank you for inviting us to discuss our progress in streamlining Medicare policies and helping providers participate in the Medicare program.

We all share the goals of minimizing Medicare regulations and maintaining and strengthening the program's efficiency and integrity. I think we also all appreciate the challenges these sometimes conflicting goals can present. The laws governing Medicare are complex and extensive, and its administration is complicated—in large part because medicine and our ever-evolving health care delivery system are complex. And Medicare, according to the General Accounting Office, is intrinsically at high risk of fraud, waste, and abuse because of its size and scope.

Provider concerns about these issues have been heightened by the Balanced Budget Act's (BBA) substantial impact on providers, and by our unprecedented success in fighting fraud, waste, and abuse, which has cut the Medicare payment error rate nearly in half. We greatly appreciate the opportunity this hearing provides to explore additional actions we might take to help providers participating in the program.

We are already taking a number of steps to review our policies and procedures for potential areas in which they might be streamlined or simplified. Last year, for example, we worked with Congress to develop the Balanced Budget Refinement Act (BBRA). We also took a number of administrative steps to help providers adjust to changes mandated in the BBA. And, as the President has announced, we want to enact further refinements to ensure that providers receive adequate payment and beneficiaries continue to have access to quality care.

We have several other initiatives underway to help providers and better target our program integrity efforts.

- We have launched a wide-ranging education initiative to help providers understand Medicare policies and how to bill correctly, and to prepare them for the new payment systems mandated by the law.
- We have formed a Physicians Regulatory Issues Team to review, clarify, and simplify rules, and ensure that clinician concerns are heard as we develop policies and guidance.
- We have worked with the HHS Inspector General to develop compliance guidance for providers, including those issued just this month for physicians, and are inviting public comments on this guidance.
- We are studying payment error rates at the contractor level so we can focus education and error prevention efforts more sharply.
- We are requiring all claims processing contractors to establish toll-free lines for providers to call with billing questions.
- We will be testing simplified evaluation and management guidelines designed to reduce the documentation required for physicians to justify their claims.
- This month we sent a letter to more than 800,000 providers on how to address the most common documentation problems.
- And we are conducting an increasing number of town meetings and other endeavors to communicate directly with providers about their concerns.

BACKGROUND

The Health Care Financing Administration (HCFA) is the largest health insurer in the nation, covering some 74 million Americans through Medicare, Medicaid, and the State Children's Health Insurance Program. It will pay about $368 billion for health care services this year. For Medicare alone, we pay out more than $210 billion each year for nearly one billion claims by some 700,000 physicians, 6,000 hospitals, and thousands of other providers and suppliers. The people who work at HCFA care deeply about serving the 39 million senior citizens and people with disabilities who rely on Medicare, and I am proud of our record of accomplishments.

The innovations we have developed in quality improvement and prospective payment systems that promote efficiency have been widely adopted by other public and private sector insurers. We also have important statutory responsibilities to ensure that quality and safety standards are met for all patients served by health care providers, as well as to support medical education.

The volume of Medicare laws and regulations covering all these responsibilities, while often greatly exaggerated, is substantial. The Social Security Act includes 900 pages of legislative language related to all HCFA programs. For all these programs including Medicare, we have issued 1,700 pages of regulations to implement this legislation. Individual providers need to understand only the fraction of these pages that relate to the specific services they provide.

Our process for developing and implementing regulations is fair and open. Providers and other members of the public have ample opportunity to comment and seek adjustments. They have extensive, rule-based information on what is and is not allowed, rather than arbitrary decisions. They have due process rights. And we are held accountable to providers and other members of the public through the Executive, Congressional, and Judicial branches of government. This, as providers know, is far different from the way private insurers conduct their business.

Virtually everything we do in regulations is in response to legislative mandates or directives. Congress is frequently very prescriptive in telling us how to implement the legislative changes it makes to our programs. This was particularly true with many of the 335 BBA provisions related to our programs, including new prospective payment systems that require substantial change for skilled nursing facilities, home health agencies, and hospital outpatient departments.

The BBA represented the agreement of Congress and the Administration to slow the growth in Medicare spending. Reducing spending by such an unprecedented amount in a relatively short time was an unequaled challenge. Virtually every hospital, physician, home health agency, skilled nursing facility, durable medical equipment supplier, and other health care provider in the country has been affected, and almost all have seen an impact on their revenues.

Such significant change with such an ambitious implementation schedule has created pressures and dissatisfaction. HCFA, of course, was the face of the BBA for providers. While the past two years have not been easy, I do believe we have done a good job, albeit not a perfect job, in implementing the law and remaining true to the law's intent, given the time frames, the competing interests of program stakeholders, and the complexity of the changes.

The BBA and the Health Insurance Portability and Accountability Act of 1996 both also included important new tools to help us prevent improper payments. The

vast majority of providers are honest and we have no intention of punishing them for honest errors. However, we have an indisputable obligation to try to pay fairly, prevent and identify errors, recoup improper payments, and root out the small number of providers who are not honest. This is a leading concern among beneficiaries, who tell us that they feel that fraud, waste, and abuse are rampant in the system. Still, moving in just a few short years from relatively lax program integrity efforts to a zero tolerance policy has been challenging for both us and providers.

But while difficult, the BBA and our successes in protecting program integrity have both been essential for preserving and strengthening the Medicare program. The Part A Hospital Insurance Trust Fund, which was projected to become insolvent in 1999 when President Clinton took office, is instead now projected to remain solvent until 2025.

Improving Guidance and Education

The need to continue with payment reforms, spending growth controls, and program integrity initiatives underscores the importance of our increased provider education efforts. We are therefore redoubling our efforts to reach out to all providers to ensure that our guidance on Medicare policies is clear, understandable, and consistent among the private insurance companies that, by law, we must contract with to process claims. We have initiated a wide range of provider educational activities.

For example, we are:

- airing satellite broadcasts to hundreds of sites across the country on topics of interest to providers such as Medicare coverage and payment requirements, new Medicare benefits, women's health and adult immunization initiatives, and more;
- surveying health care providers nationwide and analyzing data collected to develop new education strategies for reaching out to Medicare providers;
- developing computer-based training modules for providers on topics such as proper claims submission, Medicare Secondary Payer rules, and Medicare fraud and abuse efforts;
- writing articles on timely topics for fiscal intermediary bulletins and other publications targeted toward physicians and other providers;
- maintaining the www.hcfa.gov/medlearn web site to provide up-to-date, easily accessible material on a wide variety of issues, including interactive courses on the proper filing and documentation of claims;
- communicating on a regular basis through conference calls with national and state provider associations and issuing nationwide mailings on issues of interest;
- sharing feedback with providers, both on an individual and community level, about how to correct and prevent the types of errors identified in medical review of claims so we can reduce the number of improper claims among the vast majority of providers who make only honest errors; and
- working to ensure that contractor toll-free service lines are responsive to provider questions.

We also are strengthening and standardizing the way in which our contractors carry out provider education and customer service activities. We require all contractors to provide information via printed bulletins and newsletters, as well as via the Internet. Each contractor is required to link to our website from their website in order to give providers access to our Medicare learning network. We established a component within HCFA to specialize in education and training for the provider community. And we recently notified contractors that they may no longer charge providers a fee for attending training on Medicare issues.

Among the most important of our efforts to improve provider guidance and education is the development and testing of simplified evaluation and management guidelines that are designed to reduce the documentation required for physicians to justify their claims. When our Administrator, Nancy-Ann DeParle, arrived at the agency and learned of physician dissatisfaction with a new revision of the guidelines, she ordered that physicians be allowed to use either the new or old version, and instructed our staff to review the situation.

As a result, HCFA physicians started over with three goals in mind:

- simplify the guidelines;
- reduce the burden; and
- foster consistent and fair medical review.

We have developed simpler versions of the guidelines that we believe provide clear, unambiguous guidance and streamline the documentation required for clinically appropriate record keeping and verification that services were medically necessary and rendered as billed. We are going to rigorously test these new versions

in the real world of clinical practice. We will also test training mechanisms to determine the best way to help physicians learn how to use the new guidelines.

Throughout the process we will seek physician input on whether the new version revisions being tested are, in fact, better for them in the real world of day-to-day clinical practice. To begin the feedback process, we held a public meeting last week in Baltimore to lay out our proposed guidelines and discuss our testing plans with leaders of physician organizations.

Another good example of our increased education efforts is our current undertaking in preparation for implementation of the hospital outpatient prospective payment system, which was mandated by the BBA. This initiative, involving hospitals across the country, is unprecedented in its scope and second in size only to our Year 2000 provider outreach efforts.

As part of this effort, we are:

- holding nationwide train-the-trainer sessions for claims processing contractors who, in turn, are providing training for local hospitals and billing vendors in their areas;
- conducting additional training sessions for representatives from national and state hospital associations, as well as software vendors, in the coming months;
- posting training materials for providers on our www.hcfa.gov website;
- sponsoring a national satellite conference specifically on the hospital outpatient PPS;
- instructing all contractors to take immediate steps to disseminate final program information as soon as we release it, and to post these instructions on their websites; and
- encouraging contractors to publish articles in their provider bulletins and conduct outreach to get detailed information to providers.

Responding to Provider Concerns

Parallel to our educational initiatives, we are working to improve the service we provide to physicians and ensure that our regulations help, rather than hinder, the provision of high quality patient care. To do so, we have doubled the number of physicians at HCFA and put them in key positions. We have rejuvenated and sharpened the focus of our Practicing Physicians Advisory Committee to ask their advice on how our policies affect real-life clinical practice.

We also have established a new, internal, physician-led Physicians Regulatory Issues Team. This team is developing new systems to create rules and regulations that are simplified, clarified, and refined specifically to reduce administrative workloads on providers and better meet beneficiary needs.

To do this, the Physicians Regulatory Issues Team is:

- developing an "impact analysis" initiative to ensure that we explicitly address the impact on practicing physicians before and after issuing new policies or interpretations of existing policies, and has already begun piloting these ideas with some current regulations;
- developing a "sentinel practices" system to query and monitor a selection of diverse types of physician offices across the country in order to receive ongoing feedback on the real-world, day-to-day impact of Medicare rules;
- developing a "physician service core group" in which staff involved in physician-related efforts—from developing regulations to outreach and education—will work together to ensure clear, concise, and consistent communication;
- enhancing communication at the State and County level by having our regional offices develop outreach that reflects the needs and character of local physician communities;
- developing a set of "frequently asked questions" for physicians, as well as a "rules of the road" brochure on the basics of Medicare participation for physicians;
- hosting monthly conference calls with physician organizations across the country to address real-time and emerging issues, such as hospital coding, Peer Review Organization efforts, Medicare payment error estimate, and new preventive health benefits; and
- upgrading our website to provide clearer, more user-friendly information for physicians.

Other Administrative Action

We also are taking a number of additional administrative actions to moderate the impact of the Balanced Budget Act, reduce administrative workloads, and assist providers in meeting the needs of the patients they serve. For example:

- We are revamping the advanced beneficiary notices that providers give to beneficiaries when providing a service or item that may not be covered by Medicare. The goal is to provide a plain-language, user-friendly document explaining that

a given service or item may not be covered by Medicare and that the beneficiary may be responsible for payment, so the beneficiary can make an informed consumer decision. A new draft notice for physician and other Part B services has recently been reviewed by our Practicing Physicians Advisory Council, and will soon go into the Paperwork Reduction Act clearance process, which includes opportunities for public comments. A new draft advanced beneficiary notice for home health services is already in the Paperwork Reduction Act clearance process.

- We are delaying implementation of the hospital outpatient prospective payment system until August 1. We are distressed about having to postpone the benefits of this new system for beneficiaries, but the one-month delay will give both us and hospitals needed time to be fully prepared for this substantial change. We also are asking hospitals to not collect deductibles or coinsurance from Medicare beneficiaries beginning August 1 until we notify them of the correct amount. And we will provide all hospitals with a "plain language" flyer to help explain the change to beneficiaries.
- We are expanding the number of medical devices for which "pass-through" payments will be made under the new outpatient prospective payment system and continuing to work with the device industry to determine additional devices for which these payments can be made under the law. We also have committed to making unprecedented quarterly updates to the pass-through list to ensure that the outpatient prospective payment system does not inhibit development and use of new technologies.
- We are postponing expansion of the BBA's "transfer policy" for all hospitals for a period of two years, through 2002. As a result, the transfer payment limits will apply only to the current 10 Diagnosis Related Group (DRG) categories, as prescribed by the BBA. We are carefully considering whether further postponement of this policy is warranted.
- We are implementing new policies to make it easier for rural hospitals, whose payments are now based on lower, rural area average wages, to be reclassified and receive payments based on higher average wages in nearby urban areas. As a consequence of these policy changes, rural hospitals will receive higher reimbursement. Similarly, we are helping rural hospitals adjust to the new outpatient prospective payment system by using the same wage index for determining outpatient payment rates that is used to calculate inpatient rates.
- We are helping home health agencies by extending the time frame for repaying interim payment system overpayments from one year to three, with the first year interest-free. We are postponing the requirement for home health agencies to obtain surety bonds. And we have eliminated the sequential billing requirement.
- We are helping skilled nursing facilities by refining the payment classification system in a budget neutral way to increase pay for medically complex patients.

Assisting Medicare+Choice Plans

We also have taken important steps to help managed care and other health plans participate in the Medicare+Choice program. Final Medicare+Choice regulations announced last week incorporate many industry recommendations. They include several provisions that reduce administrative requirements for plans while maintaining strong beneficiary protections.

For example, they:

- permit flexibility to tailor benefits under M+C plans through the use of full-county segmented service areas with differing benefits;
- reduce quality assurance requirements for Preferred Provider Organizations, as defined by the statute;
- implement deeming procedures and expansion of deemable categories to include not only quality assurance and confidentiality requirements but also access standards, advance directive requirements, and provider participation and anti-discrimination requirements; and
- reduce the re-entry limitation for M+C organizations that terminated participation from 5 years to 2 years.

We also earlier announced plans to modify our current risk adjusted payment system to pay more for the higher costs of providing high quality care for patients with congestive heart failure. We are developing a revised phase-in schedule for risk adjustment in conjunction with the Medicare Payment Advisory Commission, health plans, and beneficiary groups. And, of course, our proposed prescription drug benefit would result in more than $50 billion over 10 years in additional payments to Medicare+Choice plans.

We realize that health plans choose to participate in Medicare+Choice based on business decisions, but these changes and other initiatives we've announced underscore our willingness to be responsive to constructive industry suggestions by granting flexibility when possible.

Ensuring Program Integrity

Although we recognize the need to reduce the administrative workload on providers and simplify documentation requirements where we are able, we also have a responsibility to be prudent stewards of the trust funds and maintain the financial integrity of our programs. We recognize this is a delicate, but critical, balance.

Today, our efforts to identify fraud, waste, and abuse in all of our programs are more effective than ever before. From April through September, 1998, we stopped about $5.3 billion from being paid to providers for inappropriate claims. Our antifraud efforts returned nearly $500 million to the federal government, a 65 percent increase over the previous year. We have reduced the Medicare error rate by almost half since 1996, and maintained that progress in 1999. And total Medicare integrity program savings in fiscal year 1999 totaled $9.9 billion.

Yet Medicare pays 95 percent of "clean" claims submitted by physicians without asking for any medical record to confirm the accuracy of the code, the adequacy of the documentation, or the appropriateness of the service.

We realize that our efforts to reduce fraud, waste, and abuse have generated concern among some providers. As we have said time and time again, we know the vast majority of providers are honest and conscientious, and we have no intention of punishing anyone for honest mistakes. If providers do make billing errors, we want to find those errors, preferably before we make payment. But there is a world of difference between honest errors and the kind of outright fraud we have been so successful in fighting.

While some physicians have said they are afraid of being jailed for minor errors, we do not refer providers to law enforcement for minor or occasional errors. Only the most serious matters are referred for prosecution.

We have spoken with hundreds of physicians about these concerns, and repeatedly asked them to tell us if they know of any instances of improper pursuit of physicians for honest, inadvertent errors. In fact, while some 660,000 physicians receive Medicare payments each year, in the past two years, physicians accounted for only 52 of some 500 criminal health care convictions, at a time when the Department of Justice has achieved an 85 percent conviction rate on cases it takes to court.

CONCLUSION

We are committed to helping providers participate in Medicare and to minimizing the amount of regulation, paperwork, and oversight as much as our obligation to taxpayers and beneficiaries will allow. We are taking many steps to be more responsive to provider concerns, and are open to considering others that may be appropriate. The past few years have been particularly difficult for providers due to the many BBA changes and our robust program integrity efforts.

But now, I believe, we are turning a corner. We are moving beyond BBA implementation. We are strengthening and expanding efforts to help honest providers. And we are more sharply targeting the kinds of fraud, waste, and abuse that we have had so much success in fighting. I thank you again for holding this hearing and giving us yet another opportunity to address these issues. And I am happy to answer your questions.

Mr. BILIRAKIS. Thank you, sir. You know in addition to trying to understand as much as possible all the complex legislation that goes through this House of Representatives that we have to ultimately vote upon in committee, if you will, in subcommittee and certainly on the floor, I have found that the most difficult part of our job is trying to understand the consequences of our acts, the unintended consequences, if you will, that quite often result from things such as BBA-97 and things of that nature.

I have always been curious, Michael. We all get ill, so we all go to doctors. That is one thing about health care, we can talk about an awful lot of issues here in the Congress, but many of them we personally, we Members of Congress have not personally experienced.

But when it comes to going to the physicians, to the providers, we all do that, I think. Certainly, if we don't experience it ourselves we do it with members of our family. You know, every time I go in and the doctor finds out that I am out in the waiting room waiting for my wife or whatever the case may be, obviously, I get a visit right away and an invitation to come in and sit down with the people who do the coding and things of that nature.

I guess the thought comes to my mind, maybe a fundamental question, how much of that, the actual real world type of experience, does HCFA do in the process of doing their job?

Mr. HASH. Well, Mr. Chairman, I think we need to do more of it. Clearly, the ability to assess both before we make policies and after we put them into place, what their impact is is a responsibility that we have.

We are trying to use more effectively some of the resources that I referred to in my testimony regarding the Practicing Physicians Advisory Committee, and the new internal group called the Physicians Regulatory Issues Team. These are ways in which we are seeking to reach out and evaluate more appropriately, and more rapidly, the effect of our policies.

We also have a huge obligation, I think, Mr. Chairman, and probably not sufficient resources to provide education and technical assistance to individuals who are participating in our programs.

That is an enormous challenge and one where now we are trying to add a lot of resources related to phone lines for providers and physicians to get help and information. We are trying to do more educational programs.

We now have on our web site self-training programs for physicians that are free of charge that they can download that helps them to understand how to code and how to answer questions about common billing issues.

We need to do more of that. That is very important in supporting the providers who are serving our beneficiaries and that is what many of our initiatives are about.

Mr. BILIRAKIS. Well, I know that you are an awfully busy guy. God knows you have a pretty tough job. I think we all recognize that, even those who chose to sometimes bash HCFA.

I would suggest it would be great to just take some time and go down there where the grass roots are and take a look and see what these physician providers really go through in their offices.

As I have said before, you may have heard me, 2 or 3 years ago my son opened up his own medical practice and he couldn't afford to get the computerized stuff so he used this manual method.

I spent, I guess, 2 months, our January and February break, just sitting in there trying to do as much of that as I could and seeing the complexity of the coding. So, it is quite an experience, really, quite an education. When we talk about educating them, I sometimes think we need to be more educated than they do.

The Chair will now yield to Mr. Brown.

Mr. BROWN. Mr. Chairman, thank you. I spent much of the break in a hospital observing from another angle. So, I would prefer your way next year. Thank you.

Mr. Hash, the whole complexity of HCFA which is the subject of the hearing today, the complaint from some is that the private sector is so much simpler.

Run through for us, if you would, sort of what you do when HCFA makes a decision in terms of the process that HCFA uses to develop regulations, making policy decisions, getting public input.

Run through that process briefly, if you would.

Mr. HASH. Yes, sir. Generally, Mr. Brown, we are subject to something called the Administrative Procedures Act, which governs all executive branch agencies as they make rules that have the effect of law to those who are subject to them.

That process requires consultation with interested stakeholders, affected stakeholders. It requires generally the publication of proposed rules with opportunities for comment, but then of course requires us, after the comment period is closed, to respond to all of the comments and indicate why we didn't accept them or if we did accept them, why we did agree with the commenter.

Then we put the regulations into final form. That process is subject to extensive review within the executive branch. Once the Health Care Financing Administration completes any rule or regulations, it is then reviewed by the Department of Health and Human Services because these are ultimately under the law regulations of the Secretary.

Then the Office of Management and Budget also reviews them for their consistency with the programs and the policies of the President. So there is a lengthy review process for all of these.

Mr. BROWN. How long does it take generally for the whole process and how much of that time is sort of open to public comment where providers and others affected can have very specific input into the process?

Mr. HASH. Well, typically when the Congress passes new legislation that requires the issuance of implementing regulations. We have a whole series of meetings, usually, when we are meeting with providers to get their input on what they think the implementation rules ought to look like.

That is followed by us putting together, over a month or 2, an actual proposed rule, which we then publish formally in the Federal Register. Then interested parties again have an opportunity to submit written comments to us and many organizations and individuals not only submit written comments, but also come in and meet with us during the comment period to amplify their concerns and recommendations. After the closure of that public comment period, we are required to review all of the comments, to respond to all of them in the preamble of the final regulation, and then publish the final regulation with our final decision.

Mr. BROWN. Once it is published in the Federal Register for public comment, you typically gets hundreds, thousands, tens of thousands, what is typical?

Mr. HASH. It depends on the rule. Typically it is several hundred on any major rule. But on occasion, for example, we published rules modifying the conditions of participation for hospitals. We received over 60,000 comments on that set of rules alone; 20,000 of which were related to a specific issue in that particular regulation.

So, it can go all the way from several hundred, which is routine, to several thousand.

Mr. BROWN. Now, contrast your decisionmaking process to what we might see if Medicare over time is just turned over, is just privatized, turned over the private sector one way or the other and in the process of HCFA today with the process of private insurance when it makes decisions in the area of developing and implementing payment policy decisions, education material, what plays out that way?

Mr. HASH. Well, I think for the most part, Mr. Brown, private insurance plans don't have the obligations and responsibilities that the Medicare program has on behalf of its beneficiaries. For example, we have rules and regulations about appeals and grievance procedures.

There are usually no such arrangements in private health plans. We have rules on monitoring the quality of health care services and to ensure that quality improvement is going on. To my knowledge, not much of that is done in private plans at all.

We have requirements to implement very specific payment policies associated with our programs and generally speaking private plans announce their payment arrangement, sometimes negotiate with providers, sometimes don't.

Last, we have a very large obligation to go through a public and transparent process for determining the coverage of the program for specific services and items. Many private plans don't have any public coverage review process. They just announce by fiat what they are covering and what they are not covering.

So, it is a very different environment largely driven by a much greater array of responsibilities that we have relating to our beneficiary protections, to quality, to coverage of our services and to payment of our services.

Mr. BROWN. Last question, Mr. Chairman. So, if we were to follow a sort of insurance company prescription drug program, you would see a very different HCFA versus using private insurance in terms of formularies and in terms of extent and breadth of coverage, all of those issues. You would see a very different prescription drug plan?

Mr. HASH. That would be correct because it would be subject to decisions about marketing on behalf of private insurance companies, what kinds of plans and under what circumstances and in what areas they would make those plans available.

Mr. BILIRAKIS. Mr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman. I have always thought that it would be interesting to more often have panels constituted where, for instance, we could have the HCFA representatives sitting at the same table with some of the other people giving testimony today and let you go back and forth a little bit more.

Mr. BILIRAKIS. The trouble is, I don't think HCFA would go along with that. We have tried that in the past.

Mr. GANSKE. Mr. Hash, would you have a problem with that?

Mr. HASH. Speaking on behalf of the administration, I believe that we have a policy at the Department of Health and Human Services that representatives of the administration would typically appear on their own.

Mr. GANSKE. Well, let it be noted for the record that if I were running HCFA I wouldn't mind sitting at a table and answering some questions in public.

Mr. HASH. I understand, Dr. Ganske.

Mr. GANSKE. On the other hand, I am not asking for the job. I just want to make that clear.

Well, let me take some of the questions that some of the others have because they won't be able to ask you this directly.

Dr. Coble, who is testifying for the American Medical Association, points out that carriers generally refuse to answer physicians queries in writing and that physicians should be able to obtain a file copy.

The question later arises, when I was in practice, for quite a while Medicare would provide me with a pre-authorization for certain reconstructive procedures. Let us say a breast reduction on an elderly woman who had huge breasts that were causing a lot of back and shoulder pain and deformity and problems.

That is typical practice for HMOs, for traditional indemnity insurers. One would examine the patient to make estimates for the amount of weight to be resected, even provide an authorized photograph from the patient to the insurer, not with any faces included, obviously.

Then you would get a determination from the insurer and it used to be that Medicare would do the same thing. But then a number of years ago Medicare stopped doing that. Instead, they would write a letter to the beneficiary saying, "Well, you can go ahead and have this procedure, but if we decide after you have had the procedure, then you are going to be responsible for the cost."

Now, was that just my local carrier's decision or was that a nationwide policy? This also has to do with a whole bunch of other procedures, types of eye procedures, and other things like that?

Mr. HASH. Dr. Ganske, I actually don't know offhand, but I would be happy to find out and supply for the record when that changed and why it changed. But I would assume that it has to do with resources and workload.

We have a very substantial volume of claims, as you know, 660,000 practicing physicians around the country. I think our ability, and therefore our contractors' ability, to actually provide preauthorization for a large volume of potential services was something which we could not finance.

Mr. GANSKE. With all due respect, Mr. Hash, it occurs anyway. It just occurs afterwards for a lot of these procedures. So that if the patient does decide to take the risk of being financially liable and goes ahead with it, then in every situation like that——

For instance, let us take an eye surgeon where a patient has eyelids that are hanging over their eyelashes and restricting their peripheral vision so that when they are driving down the street they can't see a car alongside of them.

That is typically something that if you would do that procedure, every time HCFA would ask for documentation of visual fields or that the procedure was necessary. But it would occur after the procedure.

So, there is no saving any time there for the bureaucrats. It is just simply a matter, it seems to me, that you are trying to scare patients from getting medically necessary procedures.

So, I want to ask you, will you reconsider that type of policy and start to allow prior authorizations?

Mr. HASH. I would be happy to look at it, Dr. Ganske, and see what the reasons are for why it is the way it is. I just don't have that information available to me.

I would say that the kinds of examples that you are giving me tend to relate to what we would call "non-covered services," potentially. The issue here is distinguishing, as you know, between what would be an elective cosmetic kind of procedure versus what is a medically necessary procedure under the rules of the Medicare coverage.

That distinction that you made very clearly here is the one that carriers are obligated to make when they get a claim that involves the provision of services that potentially may be non-covered services.

[The following was received for the record:]

The law did once require prior authorization by Medicare Peer Review Organizations (PROs) for certain elective surgeries in order for payment of claims by Medicare carriers. However, the vast majority of surgeries were approved and the requirement was perceived as unnecessary red tape by many physicians. The requirement was repealed in the Social Security Amendments of 1994. There now is no requirement or specific authority under the law for prior authorization of claims by either the PROs or the carriers. The law merely requires that carriers determine whether a claim is for medically necessary services upon receipt of the claim.

Whether there may be an appropriate and cost-effective role for prior authorization in Medicare is something that we are now exploring. Specifically, we are exploring the feasibility of a program for voluntary prior authorization for hospice services. This effort is in response to concerns that the benefit is under-used due to the difficulty in determining that a patient has six months or less to live and is therefore eligible for the benefit under the law.

Mr. GANSKE. Well, you might as well——

Mr. BILIRAKIS. Without objection, the gentleman is given an additional 2 minutes.

Mr. GANSKE. Thank you, Mr. Chairman.

Mr. BILIRAKIS. That shocked you; didn't it?

Mr. GANSKE. It isn't just reconstructive procedures that we are talking about. There are other types of procedures as well. You know, it is that type of a hassle that both patients and providers go through that drives them nuts.

It is hard for me to understand how in the end it is saving the HCFA any work unless you are scaring beneficiaries from having the procedure done that they need and then they just don't pursue it. And I don't think you want to do that.

Mr. HASH. No, Dr. Ganske, definitely not. We want to make sure that our beneficiaries get services to which they are entitled and to which they are entitled under our programs.

Mr. GANSKE. Well, what I would like is, I would like a letter back from you specifically addressing that. This is the type of thing, then, if there isn't a common sense solution, then you are forcing Congress to become much more prescriptive and proscriptive in terms of its legislation which I think then complicates your job.

I appreciate the extra time, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Ms. Capps may inquire. Ms. Capps, you are welcome to have 7 minutes.

Ms. CAPPS. That is very kind of you in advance.

Mr. Hash, thank you for being present here. If you wouldn't mind, I would like to continue along the lines that I began in my opening statement.

Mr. HASH. I suspected that you would.

Ms. CAPPS. Again, this is a good opportunity, I think, for us to discuss some of these issues that are on the minds of many of my constituents.

This has to do with the speed at which Medicare covers new technologies. For example, when the President announced a few weeks ago that Medicare will begin paying for routine costs associated with clinical trials, this was good news.

My question, and I will be as brief as I can to allow you to explain how you are doing that, but even more, what else are you doing in this kind of area? For example, I understand the agency is going to make additions this very week to the outpatient pass through list, products that serve a unique patient population.

Many clinical trials that fall under that have no alternative therapies available to them. If these products don't make the list, therefore, patients don't get access to them starting August first. What adjustment can you make or hope that you can give these people?

Mr. HASH. Let me mention three things, if I could. First, with respect to coverage of routine costs of Medicare beneficiaries in clinical trials, as the President announced several weeks ago, what we are doing is implementing recommendations that were made by the Institute of Medicine about Medicare's participation in clinical trials to make it clear that when our beneficiaries voluntarily elect to participate in an approved clinical trial, that the routine costs that would otherwise be covered for them but for the fact that they are in a clinical trial would not in any way be withheld from coverage for those individuals.

So, we are going to be putting forward notices to our contractors so that they in fact will recognize and cover the costs of individuals' routine costs associated with the provision of clinical trial services. So, that is well under way.

Second, as you know, about a year ago we began a very extensive and fundamental change in our coverage process in general in Medicare, how we recognize new advancements in health care delivery. That is now a transparent public process.

We created a FACA compliant, a Federal Advisory Committee compliant advisory group on coverage policy of over 100 distinguished scientists and clinicians from around the country. We committed ourselves to a set timeframe of 90 days. We committed ourselves to evidence-based decisionmaking and we are putting up on our web site all of the applications for coverage decision process, where they are in the process, so that the public can not only participate in this process, but is fully aware of the status for these activities.

Last, in connection with the outpatient hospital payment system, what we have done is, as you noted, we have tried to work with the industry, particularly the device and drug industry, to make

sure the pass-throughs to which they are entitled for new technologies that have come about since 1996 are recognized for pass-through in our outpatient system.

We are also recognizing that there are going to continue to be new advancements in devices and drugs and therefore, we committed to quarterly update the technology pass-through provisions that were put into the Balanced Budget Refinement Act.

So, in a number of ways I think we are trying to address the issue of the rapidity and the openness of the process by which we make coverage decisions and bring advancements in health care rapidly to the bedside or to the clinic site for our beneficiaries.

Ms. CAPPS. That is great. Just to clarify it a little bit more, maybe this is getting too picky, but in the BBRA of 1999 cancer and orphan drugs have to automatically need to make that pass-through list.

But if an orphan drug whose application was otherwise complete has been left off the list, what is the process then that they would have to go through to get it on before August first, for example?

Mr. HASH. Well, what we did was, we set a deadline back in the spring of the first of April for device and drug companies to give us information about any items that we did not already have on our pass-through list. We got over 300 applications.

I think we announced in May about 230 of them had been approved for the first quarter of the new payment system. We have since been meeting with the device industry and have found a number of errors that we made, or omissions that they may have made in their submissions.

We are about to announce, as you mentioned a moment ago, probably an additional hundred items by the end of this week, which will be effective for the payment system in August.

For any that are still not approved in-house, we will be reviewing and completing our action on them in time for the October first quarter update and there will be quarterly updates for each quarter thereafter.

Ms. CAPPS. This sounds promising to me. Do you feel there is good enough connection between what you are doing and the providers? Is the website the best way?

Mr. HASH. I think it facilitates it. We have also been doing a lot of meetings with not only the Association of Manufacturers but also individual manufacturers themselves.

I think because of the nature of this new system, we have had to develop a much closer working relationship with the biotechnology and the drug and device industry than we previously had.

That has not gone, initially, as smoothly as we would have hoped and liked, but I think over time this process of having quarterly adjustments to the outpatient payment system will ensure that new things that come on to the market that are approved by the FDA will be made available to our beneficiaries in the outpatient setting.

Ms. CAPPS. Thank you. In our next panel, perhaps we will hear another side to this, but I also am hopeful that this is a way to think about HCFA in general, that it is much more responsive to the provider community as well as to the drug and device manufac-

turing community, that there is a communication that doesn't have to go through lots and lots of red tape.

I don't know if there are other ways that you can see this being applied to the agency in general.

Mr. HASH. Well, I think our coverage process that I mentioned, I mentioned a broader one that we are doing as of last July. We started a cycle of 90-day reviews.

I think of it as really greatly compacted and accelerated, the process by which we go through and evaluate new things, new techniques, new procedures that have been developed for medical care and health care and hopefully can evaluate them based on evidence more quickly and then make them available under coverage to our beneficiaries much more quickly than has been the pattern in the past for Medicare coverage decisions which frequently took several years.

Mr. BILIRAKIS. Dr. Norwood is recognized for a "hard" 7 minutes.

Dr. NORWOOD. Thank you, Mr. Chairman. I have my own line of questions, but I can't, Mr. Hash, leave this alone, what Dr. Ganske brought up to you about pre-authorization. First of all, it is totally unrealistic, in my view, for you not to simply tell the patient and tell the provider will you cover this or won't you? In the situation which he described, in which you are basically saying to the patient, "Well, go ahead and have the procedure and we will decide later if we will pay for that benefit" first of all has a very chilling effect on many patients receiving the treatment that the physician has prescribed for them.

I can't for the life of me understand how that is useful to you frankly to not pre-authorize things like this and let people know if it is or isn't covered.

Now, if it isn't covered, why don't you just say so?

Mr. HASH. We try to, Dr. Norwood. I really think this is an issue that involves resources, about being able to make those decisions in a timely manner prior to the provision of the service.

But as I indicated to Dr. Ganske, I intend to get back to all of you about why we have discontinued that practice and for what reasons.

Mr. NORWOOD. Let me ask you, and Dr. Ganske can correct me if I am wrong, but generally this is not an emergency procedure. The case he used, the breast reduction, and I know what you are concerned about, it is do you really medically need that or is this cosmetic.

But basically, I don't understand. If you want to be the administrator, then you have to be the administrator. That is not the way, in my view, to save money.

I want a copy of that letter, too, because I am anxious about that, too.

I want to review some of your testimony to make sure I have it right. I understood you to say that you have 660,000 physicians that you deal with around the country. In reviewing their claims and looking for waste, fraud, and abuse, you typically look at about 1 percent. Over the last year you have actually found some claims where abuse at least has taken place.

What percent of those have you found guilty of abuse?

Mr. HASH. Well, we had an audit by our Inspector General of the accuracy of our claims processing system. they determined on a sample basis that we in fact had an error rate of close to 8 percent, 7.97 percent.

So, I think the empirical answer based on their work was we have an error rate of about 7 percent.

Mr. NORWOOD. But you said you had actually believed 52 cases in which you had found them guilty?

Mr. HASH. Those were actual convictions of individuals who were convicted of criminal fraud in the Medicare Program who happened to be physicians out of a universe of a much larger number. Of 500 convictions for Medicare fraud, only 52 of them were physicians.

Mr. NORWOOD. Of that, did that return any money to the Treasury?

Mr. HASH. Yes, sir, it did. Well, I should say not the conviction itself, necessarily, but the claims that were subsequently not paid, or were collected on, resulted in collections to the Treasury and to the trust fund.

Mr. NORWOOD. Can you compare for me the cost of the review versus the return to the trust fund?

Mr. HASH. Well, I can't, Dr. Norwood, but I would be happy to try to get it together because a lot of the cost of the review is associated with the costs that were incurred by law enforcement to actually develop the prosecution and make the case.

[The following was received for the record:]

On average, the return is $17 for every dollar spent on cost review. We file a biannual Medicare Integrity Program savings report, which provides greater detail on savings from medical review, Medicare secondary payer, and cost report auditing. We do not claim savings from fraud referrals. Those referrals are counted by the Office of Inspector General and the Department of Justice (OIG/DOJ) and are referenced in their own reporting on Health Care Fraud and Abuse Control (HCFAC) funds. According to a 1999 report they released in January 2000, prosecutors filed 371 criminal indictments, convicted 396 defendants, won or negotiated $524 million in judgments, settlements and administrative fines, collected $420 million from those activities as well as prior year obligations, returned $369 million to the Trust Fund and $4.7 million as the Federal share of Medicaid restitution. The HHS Inspector General excluded 2,976 individuals from participation in the Medicare and Medicaid programs. The HCFAC account was appropriated $137.5 million in 1999, and the FBI was appropriated a separate $66 million. We would defer to the OIG or DOJ as to whether they supplement the HCFAC money with direct appropriations.

Mr. NORWOOD. Would you do that for me, Mr. Hash? I am not questioning you here at all. I am curious, is that a wise expenditure of money, looking at the big picture of the trust fund?

Mr. HASH. Most of those expenses are not from the trust fund, Dr. Norwood. They are from the budgets of the law enforcement agencies, either the Inspector General's budget at HHS or the Department of Justice or the U.S. Attorneys offices around the country.

Mr. NORWOOD. I understand. But it all comes out of the same pocket, whether it goes to the trust fund or whether it goes to the Treasury to be used at Justice, that taxpayer back home is paying that now.

Mr. HASH. That is correct.

Mr. NORWOOD. Do you think the 7 percent mistake rate, I guess that's the way to say that, do you consider that high or low?

Mr. HASH. We consider it too high. We have indicated that when we started having these audits back in 1996. Our error rate was then about 14 percent. We have cut it in half, but we have set a goal of less than 5 percent for claims error rate on a volume of 1 billion claims a year.

Mr. NORWOOD. If you were to stack your regulations up on this desk, how high would they go?

Mr. HASH. Well, I don't think they would go as high as some people think they would. We have about 1300 pages in the Social Security Act for the Medicare Program, about 900 pages, I should say.

We have about 1300 pages in the Federal Register in codified Federal Regulations and we have a number of manuals and other issuances that also support and explain the Medicare Program.

Mr. NORWOOD. A foot would be okay, wouldn't it? I wouldn't be out of line saying 12 inches high worth of regulations?

Mr. HASH. Not for regulations, it would not, no, sir.

Mr. NORWOOD. The rules that a physician has to be aware of in order to treat a Medicare patient?

Mr. HASH. Well, I would be happy to go through and give you the actual count of pages associated with-or submit it for the record.

Mr. NORWOOD. Dr. Coburn says his are 18 inches high. So, that is good enough.

My point though is, considering that it is the job of the physician to make the patient well, and he has 18 inches or regulations to follow from HCFA, do you still say a 7 percent honest error rate is out of line?

Mr. HASH. The 7 percent error rate is too high. That is a very significant amount of dollars, public dollars, that are at risk as a result of that. We don't feel like we are doing our job as stewards of the program to tolerate an error rate of 7 percent.

Mr. NORWOOD. Are you doing anything in your job to lower that stack of regulations from 18 inches to 12?

Mr. HASH. Yes, sir, we are. I tried to identify some of those steps in my testimony.

Mr. NORWOOD. I will yield. Dr. Ganske, do you want to have a follow up?

Mr. BILIRAKIS. Well, you don't have any time left.

Mr. NORWOOD. Okay. I yield back.

Mr. BILIRAKIS. You yield back zero, yes.

Ms. Eshoo is recognized to inquire.

Ms. ESHOO. Good morning, Mr. Chairman. Good morning, Mr. Hash, it is nice to see you. I think after trying to make optimum use of the time we have, 5 minutes, I am going to try something new.

I am going to read all of my questions and then give them to you because usually once the witness gets the first question, you don't' get to ask the second and the third. Let me just start out that way.

But let me thank you, Mr. Chairman, for having this hearing because I think that there are a whole host of issues that really fall into the realm of this hearing. I think that it is well timed.

I have long been concerned about delays at HCFA because a delay, I believe, represents preventing Medicare beneficiaries from benefiting from the best that medical technology has to offer in our

country, certainly at the high end in our nation we know that we have the best. I mean it is absolutely second to none.

I understand that it can take up to 4 years for HCFA to make a coverage decision. That severely, again, delays the access for Medicare beneficiaries.

Cardiac stents, for example, were available on the market long before they were made available to Medicare beneficiaries, and these products were available in Europe and Asia in their reimbursement systems before we did it here.

Now, I know that FDA has specific statutory timeframes within which they are required to review and approve medical technology operations.

My question is does HCFA keep track of the timeframes involved in making the coverage decision so that we can see what they are?

Mr. HASH. We do.

Ms. ESHOO. We do? Then once you keep track of them, what happens? I mean, do you acknowledge where your 3½ years flow? It is one thing to track it. It is another thing to do something with it. Is there any effort on the part of the agency, that is probably the larger question, to shorten the timeframes.

My other question is that in following HCFA on the outpatient pass-through payment list, you know that I have concerns about it. I have written to HCFA expressing my concerns with this brand-specific approach to placing products on the list.

I just have to tell you just right off the top that I think that is really faulty. Now, I guess a manufacturer whose product has hit the list is thrilled. But just for an example, rather than listing dual chamber pacemakers first, the list only includes Medtronic's Kappa 700. Medtronic even raised a question about that.

So, I really don't understand the method for the madness of this. I know that sounds so disrespectful, but it really is making an awful lot of people scratch their heads about what your process is, how well thought-out it is, and, of course, it is not just for the technology people and the manufacturer of their products, we are here to talk about the people that we represent.

You know they say that justice delayed is justice denied. Well, then I think in this case access delayed is quality patient care denied.

So, it is in that context that I ask this, so maybe you can touch on what HCFA's rationale for listing specific brands of medical devices rather than product categories. Again, I think that it seems like an arbitrary decision. So far I don't think it is so workable because you have had to go back at it.

You have people all over the country scratching their heads and they are up in arms. But if you explain it to us we might appreciate the underlying reasons.

My last question is, when FDA-and some of us have had a little more experience with this than others because we were so involved in writing the legislation that brought about the reforms at FDA relative to medical devices. There are very favorable reviews on how that is working now which pleases me a great deal.

When FDA goes through the process that it goes through so that a product is finally approved for use in our country, why is it that HCFA goes through a duplicative process? That is it.

Mr. HASH. Okay. Those are great questions. Let me take them and try to do it quickly.

First on the coverage process, about a year ago we announced a complete revamping of our coverage process. What we said was we were going to commit ourselves to specific timeframes, i.e., 90 days; that we were going to do evidence-based coverage decisions that could be initiated by any individual, any company, any beneficiary, any person.

We also created, just as the FDA had done, a national coverage advisory committee. Over 100 distinguished scientists and clinicians from around the country participate in that.

We started that process last July. We have been making decisions within that 90-day timeframe. This is for coverage under the Medicare Program.

We put up each and every application that comes in for that process on our web site. We update those entries all the time so people can look and see. We have been doing that, it will be a year this July 1.

So, it is a complete revamping. For all of the reasons that you just said is why we did it. We are putting together additional guidance on the criteria that we are applying in that coverage process and as the FDA has done, we are developing sector specific guidance for devices, for drugs——

Ms. ESHOO. That is what I don't understand. This sounds like a very tidy, needed process. But if, with what you just described, why you ended up in the mess with this outpatient pass-through payment thing?

Mr. HASH. That is question two.

Ms. ESHOO. How does one thing lead to the other?

Mr. BILIRAKIS. Brief response now, because the 7 minutes are about up.

Mr. HASH. The brief response is that the BBRA, last December when it was enacted, included direction for us to modify our outpatient payment system to recognize products that came on the market since 1996, which is the base year for establishing the outpatient payment rate.

So, we had to identify which items of new technologies were actually put on the market for the first time after 1996 and therefore wouldn't be reflected in the data for the rates that were being established.

That was a process that we believed required an item-by-item review. That is what we have done. We are cognizant very much of the desire of people to move to a categorization scheme where in fact you would group like items and do it that way.

The difficulties are, one, the categorization scheme does not exist.

Ms. ESHOO. What does that mean?

Mr. HASH. That means there is no agreed upon system for grouping hundreds of different devices that are similar and what defines what is similar and what is different enough to be in a different category.

Furthermore, the way the law is written, if you had an item in a category that was actually on the market prior to 1996 and the rest of the items came on to the market after 1996, that whole cat-

egory would not be eligible for the pass-through which is an outcome I don't think people would like to have happen either.

Mr. BILIRAKIS. The gentlelady's time has long expired.

Ms. ESHOO. Mr. Chairman, can I just state something for the observation of the committee?

Mr. BILIRAKIS. You are in the 9th minute.

Ms. ESHOO. Oh, all right.

Mr. HASH. Mr. Chairman, I would be happy to get back to you on that.

Mr. BILIRAKIS. Yes, I think that is necessary, certainly in writing, too.

[The following was received for the record:]

We have been engaged in discussions about the OPD pass-through issue with device manufacturers. As we have explained to them, there are significant problems with the category approach they have proposed. To be eligible for a pass-through payment, the law requires that, "payment for the device, drug, or biological, as an outpatient hospital service under this part was not being made as of December 31, 1996." As a result, many of the devices we have approved would likely not have qualified under the category approach. That is because, under a category approach, if any device in the category was being reimbursed by Medicare as of December 31, 1996, the entire category of devices would not be eligible for pass-through payments. I do not believe that this is the result Congress intended (nor a result device manufacturers would desire). Nevertheless, we have indicated many times our willingness to continue to work with device manufacturers and with the Congress to address your concerns and to provide technical assistance should Congress decide to make revisions to the statute.

Mr. BILIRAKIS. Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman. I actually was going to ask some questions about the documentation requirements for the CPT 99215 and then after I started going through the seven pages, it was so complicated that I decided I was going to give that to Dr. Coburn to ask. So, he will talk to you about that, I think, maybe.

Mr. COBURN. Don't worry. I will.

Mr. WHITFIELD. One of the questions I wanted to ask you, relating to audits, which I know is very important, but it seems to me some of the testimony that I have read about post-payment audits and the testimony here is that physicians should enjoy the same due process rights as taxpayers undergoing IRS audits, who can appeal IRS fines, penalties and findings.

It says that once Medicare conducts an audit or a carrier conducts an audit and they arrive at a projected overpayment amount by extrapolation, that a physician has three options: One, they can repay the extrapolated amount and waive their appeal rights. Two, they can repay the extrapolated amount and submit additional information while waiving their appeal rights. Or three, they can just open up their practice to a statistically valid random sampling of claims during the same period.

So, your manual actually prevents physicians from retaining their due process rights unless they agree to open up their practices to a larger SVRS audit. Now, I would like to know what is the rationale for that type of practice?

Mr. HASH. Mr. Whitfield, that practice is actually not a widespread practice in terms of what our carriers do in terms of doing sampling and extrapolation. But when it is used my understanding is that physicians do have the option of not waiving their appeal

rights if in fact they want to challenge the basis for either the judgment about the individual claims in the sample or the validity of the extrapolation itself.

Mr. COBURN. Would the gentleman yield? This is exactly the same situation where we were with IRS. You can do that, but any claim you file, they are not going to pay you. They are going to take the money out of the claim. So, in fact, you have given up all rights.

So, to answer in that way, Mr. Hash, is actually not correct, because you don't have any rights once they say you owe them the money. You are going to take the money from them; correct?

Mr. HASH. I believe that is correct.

Mr. WHITFIELD. Then also, I noticed that if a physician determines himself or herself that they received an overpayment and they pay that back, evidently HCFA has instructed its carriers to begin auditing physicians who submit too large of an overpayment remittance.

Mr. HASH. I have heard that, Mr. Whitfield, but the best that I have been able to do to get an answer to that is that I cannot in fact find any evidence that that is going on. But I would certainly be open to further inquiry.

We don't intend that that be the policy at all by our contractors. I have been inquiring about that and have been unable to find any written instructions to that effect.

Mr. WHITFIELD. So you would actually encourage the repayment of overpayments voluntarily then, I am assuming.

Mr. HASH. We would, yes, sir.

Mr. WHITFIELD. But this testimony says that HCFA has instructed its carriers to begin auditing physicians who submit these overpayments.

Mr. HASH. If I am in error, I want to correct that. I knew this was an issue that was going to be raised. I am unaware that we have done any of that kind of instruction.

Mr. WHITFIELD. Just going through some specific rules here, I could go through some relating to hospitals, but I just have the physician rules before me.

It says a rule proposed in 1997 which still has not been finalized, details position supervision requirements for numerous office procedures.

The regulation actually dictates during which procedures a physician must supervise from within the office suite, but not necessarily within the examining room.

It seems to me that when you are dealing with these physicians who are professionally trained that this removes a lot of flexibility from them. I was just wondering if you might comment. It is so micro-managed that I guess you will reimburse if oversee it or supervise it within the examining room in some instances and in the office suite in other instances.

Mr. HASH. That is correct, Mr. Whitfield. I know we have in our regulations standards that distinguish between what we would call general supervision which means that for individuals who are employed by or contracted by a physician, the physician needs to be present on the premises where the services are being rendered.

Then we have under some circumstances a requirement that the physician must be physically present during the service provided by another health care professional.

Mr. WHITFIELD. Can you give an example of one or both?

Mr. HASH. It has to do largely with the license restrictions on these non-physician practitioners and what they are able to do without direct supervision and what requires direct supervision. I would be happy to get you a list of those kinds of circumstances, but I think it involves services such as some of the therapy services by therapy assistants.

It turns very much on the qualifications and license restrictions of the individual health care professional vis-&-vis the physician who is employing or contracting them.

I would just say in general, the reasons for these requirements, as they are for the licensure requirements, is to ensure that quality of care is provided by people who are properly credentialed and properly supervised.

Mr. WHITFIELD. Speaking of that, where are you all on this decision regarding anesthesiologists and nurse anesthetists? Are you all coming forth with something?

Mr. HASH. We have separated that particular part of the rule which was published in December 1997 which was the hospital conditions of participation regulation and we are pulling that piece out and expecting to finalize it this summer.

At the time, about a month ago, when we made this decision, the administrator communicated with a number of folks in the Congress indicating that it was our intention to finalize this reg as we had published it in the Federal Register. The regulation is now in clearance.

Mr. WHITFIELD. Mr. Chairman, I assume my time has expired.

Mr. BILIRAKIS. Yes. Dr. Coburn will inquire. You have 7 minutes.

Mr. COBURN. Mr. Hash, welcome. The intensity of my questions are no reflection upon you. I want you to know that. I am a thoroughly frustrated family practice doctor.

You know I have a question. Why is it your carriers interpret different things? Why is it one carrier will tell me one thing and another will tell me something else? Where is the breakdown in the system that we don't have one Medicare agency, that we have several and that if I ask exactly the same question in written form I get a different answer with a different interpretation.

Why is that?

Mr. HASH. The reason I think largely, Dr. Coburn, is the historical fact that when Medicare was enacted in 1965, the plan was to do the administration of the program through private contractors, basically private insurance companies.

At that time, it was felt that those insurance companies had the expertise and the experience about what local medical practice was like and the expectation was they would attempt to conform the Medicare Program.

Mr. COBURN. I understand that. Why now?

Mr. HASH. Well, now we have been trying to take steps to move toward more uniformity and consistency.

Mr. COBURN. How can it not be uniform when you all send in exactly the same information on "here is what we are going to do?"

Why is it not uniform? Why is it the family practice or the ACOG or the Society of Surgeons or the AMA can't get something that is the same throughout the country as far as the rule?

Mr. HASH. The reason for that is that within the scope of responsibilities, carriers, contractors, they have discretion under the leadership of their medical directors to make certain decisions and to establish publicly local medical review policies which can vary from one contractor to another.

We are trying to evaluate whether or not we should move to a different system which restricts the ability of local carriers to make individual local medical review policies and to remove that discretion from those contractors.

We have not arrived at that decision yet, but the reason there are differences is that there is a good bit of discretion at the local level for carriers to establish review policies on their own based on evidence and judgment that they bring to bear.

Mr. COBURN. I just thing that is poppycock. We are not treating pneumonia different throughout this country. We are not seeing a person longer in Muskogee, Oklahoma than we are in Columbus, Ohio for the same thing. That may be 1965 policy, but that is ludicrous, especially in light of your practice parameters and guidelines and recording.

I want to spend some time on that. Congressman Whitfield brought up a Level 5 office visit. I want to tell you, and I talked to Paul before this was instituted and I want to tell you it is happening.

Is it in fact the case that when you all go in to audit and you decide that somebody has a 7 percent or an 8 percent upgrade, that your penalty for that is you apply that over all the payments that you made that year.

In other words, you put the "retro spectroscope" on it and you assume, based on what is in the medical records of the few charges that you audit that they are guilty on everything; is that not the policy?

Mr. HASH. We use what is called the sampling technique that has been statistically validated and from which we extrapolate the likely rate of error.

Mr. COBURN. Out of that 7.97 percent error rate, how much of that do you perceive is up-coding?

Mr. HASH. We have not been about, actually, I should say the Inspector General has not been able to break down the individual reasons for, or the causal factors for, the error rate, except it falls into, from their point of view, four areas.

The largest area of error rate from their audits has consistently been the failure of the medical record to support——

Mr. COBURN. That is up coding. That is exactly what I am asking you. The point is you all have set in place a rule that is driving every doctor in this country crazy. Here is the rule: If it is not documented in the chart, completely to the satisfaction of somebody outside, then you didn't do it.

Now, here is what is happening. We have wonderful computers now. I can generate you the biggest line of medical BS that is going in the record. It is going in all across this country.

When you go in to audit it, you are going to find that it meets everything that you need. But it has nothing to do with reflecting that patient's condition because over on the side is going to be the scribbling, mine, that you can't read and I can barely read, to tell me, because I know if I fail to make proper everything I said to that patient after seeing 22 patients that day and not getting a chance to dictate it at the time, that in fact you are going to come in and kick my rear.

So, you all are ruining the quality of care in this country because the medical record means nothing now. In your attempt to make it mean something to say every physician in the country is cheating Medicare, you have destroyed the quality of the medical record.

My question to you is, when you have everybody down to where we have a computer-generated office visit that meets everything that the government wants and care declines because we don't have a consistent record, and then you spend twice as much money on the patients, haven't we really shot ourselves in the foot?

Mr. HASH. Dr. Coburn, what we are trying to do, as I said in my opening statement, is to revise our evaluation and management guidelines in cooperation with physicians across the country.

We just had a town hall meeting about a week ago where we rolled those out.

Mr. COBURN. But if you continue to use that as your judgment, why don't you just say to the primary care doctors in this country, do it in blocks of time. Quit wasting your time and theirs. We know how to write a medical record. Every one of us writes a little bit different based on our own personality and what our training is.

But you are going to use your standard of judgment or your carrier's standard of judgment that says I didn't do it right.

So, you have intimidated, especially the internal medicine doctors in this country and the family practice doctors in this country into writing a bunch of stuff in the chart that will never be used, is of no value in the future except to the government.

So why don't you just say we are stopping all this. Go in blocks of 10 minutes and we will pay you by blocks of 10 minutes that will be reflective of your time. Medicare will save money. You won't have to come in and audit it. And we can save money in terms of following the response.

What is wrong with that approach?

Mr. HASH. Well, I think there are objectives here that should be complimentary to the practicing physician as well as to the program. That is, first, that we should have a standard that is fair and simple and easy for everybody to understand so that when their claims are, in fact, reviewed that they know the standards against which they are going to be evaluated.

So, that has been the major purpose for trying——

Mr. COBURN. That is right. Your standards right here for one office visit, here are six typewritten pages of the standard that has to be met for one office visit.

Mr. HASH. That is no longer the guidelines that we are working on now.

Mr. COBURN. That is the guidelines under which you were judging whether somebody up coded and did not bill Medicare correct today.

Mr. HASH. Currently, we are using two sets of guidelines, ones we issued in 1995 and 1997, and we instructed our contractors to use whichever set of guidelines was most favorable for the physician.

Mr. COBURN. Let me ask you one question and then I will yield.

Mr. BILIRAKIS. Yes, very quickly.

Mr. COBURN. If I went through a checklist in my chart and I have a checklist for all the review systems and I have a checklist for the chief complaint and then I have all the scribblings and here is my physical findings and here is my assessment and then there is a check list for when to follow up.

That is the piece of paper. Yet, I spent an hour with the patient taking a detailed history, looking at him and doing everything. The paper would never say that. But the patient got the care.

The thing that is so objectionable to physicians in this country is that you are like the IRS. We are guilty until we prove ourselves innocent. It should be about the patient, not about the doctor and not about Medicare.

HCFA is no better than the health insurance industry in terms of not caring about what really matters. That is the patient.

I am sorry about the tirade, but I want to tell you, my office is going nuts. We can't even tell from the records now because I can't read my partner's writing and the one that is typewritten certainly doesn't reflect what happened because it is computer-generated to please you.

Mr. WHITFIELD. Mr. Chairman, I ask unanimous consent the gentleman be given 1 additional minute.

Mr. BILIRAKIS. The gentleman has already taken, I think, close to 2 additional minutes. But in any case, are you finished, Tom?

Mr. COBURN. Are we going to have any additional questioning?

Mr. BILIRAKIS. I have extended the time to 7 minutes. We have another panel. That is my concern. Why don't we have Mr. Hash respond to Tom's, as he described it, "tirade?"

Mr. HASH. I don't view it as a tirade. I understand. I know there is a high degree of frustration and I appreciate that.

What I am trying to say is we are trying to redouble our efforts to work more collaboratively and cooperatively with the physician community and my testimony lays out a number of steps we have been trying to take, including the issue of documentation of services.

We need the continued support and input of physicians to get it right. As I was trying to say a moment ago, I think the balance we are trying to strike here is something that is useful to physicians because it compliments whatever they would ordinarily do as good practice and good documentation and provides us a basis for meeting our fiduciary responsibilities that we are paying for covered services that are billed at the appropriate level.

Trying to figure out how we meet both those goals, to have guidelines that are not intrusive and burdensome on physicians but have some degree of accountability for what we are paying for is what we are trying to do.

The problem with only time is that you lose in time the richness of the kinds of things that you just described that are actually

going on and for which you should be compensated under our program.

Mr. Hash, if I don't document it, you are assuming I didn't do it.

Mr. HASH. But there should be a way in which that documentation guideline allows you to display whatever——

Mr. COBURN. There is an easy way for Medicare to solve this problem. You pay doctors in terms of office visits on time and you put undercover patients out there.

It is not the internists in this country. There are certain subspecialties like cardiology where we have way too many echocardiograms, you all know that. We know it. You can't filter it out because they are great at documenting it.

Until you put undercover patients out there to get the real bad actors out of Medicare, you can't write enough rules to require us to document. You will never catch them. People that went to medical school made it out of high school. Their IQs are generally above a lot of other people's. Therefore, they know how to get around the corner.

Mr. BILIRAKIS. Mr. Greenwood to inquire.

Mr. GREENWOOD. Thank you, Mr. Chairman. Mr. Hash, a few years ago this committee spent a lot of time and effort to reform the Food and Drug Administration. One of the reasons we did is because as we looked at the pipeline between the laboratory and the patient trying to move medical devices and pharmaceutical products, we saw FDA as a bit of a bottleneck.

Obviously, they have a function that they have to perform. But we thought that this tremendous promise that continues to mount that is developed in the laboratory and the biologics and pharmaceuticals really need to get to the patient as expeditiously as possible.

We are now in the throes of trying to figure out how to add a prescription drug benefit to Medicare. It has the potentiality of the creation of another bottleneck. That is, once FDA approves the product, somebody under some model has to decide whether the patient is going to get reimbursed for that.

Would you describe for me how, under the President's proposal, when the FDA approves a product, what will happen prior to that product being available to a Medicare beneficiary and reimbursed.

Mr. HASH. Under the President's proposal, Mr. Greenwood, the agency would contract with private pharmacy benefit management organizations who are providing prescription drug coverage for privately insured people and that those organizations under our contract would be required to cover all therapeutic classes of drugs and all drugs for which the prescribing physician had requested as medically necessary for their patients. Those are the terms of the contracts that would be written with those organizations.

Then they would in fact administer the program, pay the claims, check on drug interactions and drug utilization and provide the services that they are typically providing for private health plans today.

Mr. GREENWOOD. So, there is no function that HCFA would play in that?

Mr. HASH. There is no function that HCFA would play in that process.

Mr. GREENWOOD. And how would you compare and contrast that to the legislation that the House is going to consider tomorrow in terms of those issues, in terms of the ability to get that product approved for reimbursement?

Mr. HASH. My understanding is that there would be specifications in the law that would be proposed here for the bill that is coming before the House for private insurance companies to offer policies that cover drugs only and that they would be required, if they were going to offer such a policy, to meet a certain actuarial standard for that policy.

But beyond that, they would be largely free to design their own formularies, to decide on issues between generic and brand name and how those substitutions would or would not——

Mr. GREENWOOD. Except that our legislation requires that all therapeutic categories be covered as well; does it not?

Mr. HASH. But essentially, the private insurance company that is offering the drug-only plan would be subject to whatever requirements you put into the law.

Mr. GREENWOOD. Under the President's proposal, the coverage decision is completely contracted out by headquarters. As we said earlier, HCFA needs to make-HCFA doesn't need to put a finger on the decisionmaking process.

Mr. HASH. There would clearly be an oversight responsibility in terms of ensuring that the organization was adhering to its contractual obligations.

Mr. GREENWOOD. But you would argue, not one that would delay the——

Mr. HASH. No.

Mr. GREENWOOD. I assume that you think that is a pretty efficient model.

Mr. HASH. Our reason for selecting that model is that we believe the vast majority of Americans who are fortunate enough to have prescription drug coverage, that is how they are getting their coverage today. We think that system is working for those Americans and we would like to make it work for Medicare beneficiaries.

Mr. GREENWOOD. Now let's turn our attention to medical devices. Why not apply that model to coverage decisions for medical devices?

Mr. HASH. Well, as I mentioned earlier, we put into place a coverage process for Medicare that includes devices, as well as new procedures, which is an evidence-based system, a 90-day cycle. We borrowed very heavily in designing this system from the FDA system where there are set timeframes, where there is an established outside advisory body that opines on proposals to add new devices or new procedures to Medicare.

We think that that is a transparent, publicly——

Mr. GREENWOOD. What value does that process add to what FDA has already set forth in its approval of product?

Mr. HASH. My understanding is the FDA assignment or responsibility is to determine the safety and efficacy of drugs before they go to market.

In the case of Medicare, we are applying a slightly different standard. We are taking the safety and efficacy information from FDA, but we are making a decision about whether or not under the Medicare statute the device or the procedure is reasonable and necessary which is the standard the statute sets forth for Medicare-covered services.

That is not the same standard of safety and efficacy that the FDA has.

Mr. GREENWOOD. Earlier on you were responding to a question, I think, from Mr. Brown about time sequences and you talked about how long it takes to evaluate the comments that come in sometimes, sometimes a hundred and sometimes tens of thousands.

If you had to reinvent that whole process, that is a very time-consuming process and obviously many of those comments are redundant.

Let me ask you, to what extent is HCFA actually thinking way outside the box in trying to reinvent that process so that you don't have these tortuous time delays in implementation that are caused, at least the extent to which those delays are caused by the tedious nature of evaluating, soliciting, collecting and evaluating those comments?

Mr. HASH. First, I would say we actually believe that what sets Medicare apart, what distinguishes it from private health plans is the fact that its policies are subject to public participation and accountability, both through the rulemaking process, through oversight by the Congress, through judicial oversight——

Mr. GREENWOOD. But that is a mixed blessing. What we have said is that you are erring on the side of all of that input, but there is a price to pay for all of that and that price is time.

Mr. HASH. In some degree that is true. But I think in terms of beneficiary involvement and provider involvement in formulating our policies that to not allow that to go forward would be a great loss to the program and would erode, I think, what is broad and deep public support for the public Medicare Program.

Mr. BILIRAKIS. The gentleman's time has expired. I have increased the time from 5 to 7 minutes. We have managed to run well over the 7 minutes.

Mr. NORWOOD. Mr. Chairman, that is an indication of how important this hearing is. Thank you for having it.

Mr. BILIRAKIS. I thank you for you. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman. Welcome. I apologize for my absence.

I want to ask you, in your testimony you list an impressive array of activities going on at HCFA to educate providers on how to work within the maze of Medicare requirements.

A senior official at HCFA a week or so ago on June 18 in a New York Times article was quoted about Medicare beneficiaries not being able to handle too many choices because they find them confusing.

I would think that the beneficiaries find the paperwork that they receive and have to manage with HCFA also extremely confusing. Is HCFA concerned about that?

Mr. HASH. Yes, sir. One of the things we have been trying to do is to simplify and put into plain language our communications with beneficiaries. We are doing that in several different places.

One is there is a series of notices that beneficiaries get, things like an advanced notice of coverage that we are trying to simplify so that they are plainly written and easy to understand.

Second, we have completely revamped the notices that we send to beneficiaries, which we call the explanation of benefits. This is essentially an accounting of what services they were provided and when those services were provided.

We have revamped that into something that is going to be a monthly notice called a Medicare Summary Notice that would look very much like a credit card bill. For each month, if there was activity in the sense of services covered by Medicare for an individual, they would get an aggregated monthly notice that would itemize the items, services, or visits that they received, indicate from whom and for what purpose, so that they could have a record of their own encounters and help them to navigate more easily the Medicare systems.

Last, we spent a considerable effort in launching a national Medicare Education Program last year which will continue hopefully into the future if we continue to get resources for it.

That consists of sending every beneficiary a handbook called "Medicare and You," which is mailed to their home each fall. We have a 1-800 Medicare telephone number that has individuals who are trained on Medicare policy and procedures to answer questions of our beneficiaries.

Also, we have a web site with a lot of comparative information about the health care choices that Medicare beneficiaries have, including quality and satisfaction data about health plans that is now readily available to Medicare beneficiaries to support their decisions and choices.

All of this material is now focus group tested. It is reviewed for purposes of understandability and comprehension and when you consider that, on average, the comprehension and educational level of many of our beneficiaries is still eighth grade education or lower, it is very important that we communicate in the most clear and simple manner possible so that beneficiaries are aware of their opportunities in Medicare.

Mr. BRYANT. Let me ask you a couple of follow up questions. On your Item 2, EOB, the Explanation of Benefits form, you said it would be an itemization. For those people who can review this document, would there be sufficient data on that document for them to continue as a check and balance in terms of making sure services were rendered and so forth?

Mr. HASH. That is correct. There is also a 1-800 number on that summary notice that tells them if this isn't clear, if you think there is an error here, or if you want to make a correction, call this number.

Mr. BRYANT. Let me jump over to telemedicine if I could, very briefly. HCFA's final rule implementing the Balanced Budget Act of 1997 denies payment for telemedicine store and forward application, which is widely accepted as a cost effective way to transmit an image to a remote specialist to be reviewed at a later time.

Ignoring the development of technology, HCFA has, we believe, arbitrarily ruled that in order to qualify as a consultation, all practitioner/provider encounters has to occur in real time.

Why is HCFA preventing the growth of this technology of telemedicine at a time when Congress is working to increase access to health care at all levels of society and particularly in some of the rural areas that I represent in Tennessee?

Mr. HASH. Well, I think we need to work on that together, Mr. Bryant. I think that telemedicine does offer real valuable opportunities for access to health care services by people who live in more isolated areas.

I think the problem in a nutshell is that the statutory and regulatory provisions for the codes that we recognize for billing purposes don't yet include that kind of encounter. They are all based on some kind of physical encounter between a patient and a provider of health care services.

I think we need to look and see how we can change that to make those services more available to the individuals because I agree with you. It does represent an important opportunity to deal with access questions for isolated populations.

Mr. BRYANT. I would like to follow up with you on that point. I know you will be back up here probably within the week. I would like to give you a little bit more time and maybe after our third or fourth encounter after we go through this year or next year, I want to follow up and ask you about that, if you could have some optimistic and favorable——

Mr. HASH. Yes.

Mr. BRYANT. I will yield back the balance of my time.

Mr. BILIRAKIS. Mr. Burr to inquire. I understand Mr. Strickland has no questions at this time.

Mr. Burr?

Mr. BURR. Thank you, Mr. Chairman.

Welcome, Mike.

Mr. HASH. Thank you, Mr. Burr.

Mr. BURR. Let me just start with one glaring thing that I have. That is a response to a letter I wrote in November, the response I got from Robert Berenson, M.D., Director, Center for Health Plans and Providers, dated June 9, 2000; 7 months after I made a request on clarification on three issues. I won't get into the issues. I will take them up later with you.

I would only say that for all the claims that you make and that the agency makes about the ability to stay on top of things, clearly I would hope that coverage determinations that were inquiries from Members of Congress either receive a better response than 7 months or that I haven't stumped you to the degree that it took 7 months to figure out the answer that you wanted to share with me.

I will highlight just one of the responses. It was to a reclassification of a particular procedure. The answer that I got was disturbing because it gets into an issue that you and I have dealt with at another time.

The answer basically was that we looked back at the claims that we paid. Most of them were reclassified anyway to the tune of 88 percent of the claims.

Therefore, we don't feel like we need to make a decision to change it from the lower reimbursement to the higher reimbursement because in 88 percent of the cases we already paid the higher reimbursement. I would tell you that that is not necessarily the best policy that we can adopt. I will revisit that one with you.

Mr. HASH. I apologize for the response or failure to respond. I can assure you that we are trying to work on our correspondence. It is not an acceptable excuse to say that we get literally thousands of Congressional letters a month, but we do.

They deserve and merit prompt and clear responses and we are trying to improve that.

Mr. BURR. I am just fortunate that you are able to come to this subcommittee where I can ask you in person and all the other 500 can't.

Do you plan to continue to use contractors in Medicare?

Mr. HASH. Yes, sir, we do.

Mr. BURR. You defined contractors earlier as private insurance companies. What is the different between that and what we propose to do in H.R. 4680 as it relates to private entities to administer our drug plan?

Mr. HASH. Well, in the case of what the Medicare Program does under the statute, it is that it is obligated to have the claims processing and review functions done through contracts with specified organizations which by and large are insurance companies of one kind or another.

Their scope of work, what their responsibilities are, what the policies are that they apply are ones that we include in their contracts.

Mr. BURR. You said to Mr. Whitfield and Dr. Coburn that the contractors have the latitude to address the individual needs of individual markets.

Mr. HASH. They have some latitude.

Mr. BURR. Some latitude. So, as long as the drug bill prescribed a general outline like actuarial value and some degree of certainty in the scope of drugs covered, it is not private insurers that you are worried about, it is how prescriptive we are in the legislation to make sure that this benefit is provided to everybody; right?

Mr. HASH. No, sir. I would phrase it a little differently. I would say what we are worried about, with respect to that proposal, is the fact that there is no guarantee in there that there will be prescription drug benefits that are affordable and accessible to all 39 million beneficiaries.

Mr. BURR. But the reason is not the private insurance companies.

Mr. HASH. Unless the provision is to require that private insurance companies offer prescription drug benefits to Medicare beneficiaries.

Mr. BURR. My interpretation of entitlement and specifically stating it is part of Medicare implies that it has the same rights as other Medicare services.

Mr. HASH. But it doesn't require any insurance company to actually offer such a policy; does it?

Mr. BURR. Nor does what you just described to us about your contractors because they have the latitude on some services either

to cover or not to cover; am I correct? Is it in some cases and not others?

Mr. HASH. In some cases and not in others. There is a balance between——

Mr. BURR. So, it is okay for you. It is okay for HCFA, okay for Medicare in general, but it is not okay for us under a new plan when the only difference is we use a private entity to administer it and not HCFA.

Mr. HASH. No, sir. I disagree with that. There is a fundamental difference here and that is, that for our contractors who are processing claims, they process and pay claims and are required to do so for all covered services under Medicare. They are there for certain——

Mr. BURR. But do they have the latitude to determine what those covered services are?

Mr. HASH. Only in some circumstances that are not spoken to. But it doesn't mean that they are not there doing our work under contract. It is very, very different to talk about whether or not a private insurance company might decide to open up a line of business to offer a private drug insurance policy, under what terms they would offer that, whether it would be open enrollment, community rated, all of those are issues that would be left to the marketplace.

In the case of the Medicare Program and its relationship with contractors, there is no doubt about the coverage that is there for the Medicare beneficiary.

Mr. BURR. It is a great try, but you know we are talking apples and apples. You said earlier that the goal of HCFA is for quality care provided by properly qualified and properly supervised individuals.

You are aware, I know, that there is a study, a peer review article that is ready to be published, I believe, this week or next week, as it relates to the anesthesiologists question.

Share with me, if you will, why there was such a hurry to propose a final rule and to get a sign-off on that, given that you knew that there was a very in-depth peer reviewed article that addresses this issue that was going to come out very soon.

Mr. HASH. I don't believe we have been rushing, Mr. Burr. We published the proposed rule in December 1997, so we are coming up on 3 years since the proposed rule was actually published.

Second, what I have seen, which is really an abstract of an earlier draft of the study, so I don't speak with any authority about what is actually in the study——

Mr. BURR. But you are aware of what it is.

Mr. HASH. I am aware that there is a study, but my understanding of what the study is about is a comparison of the supervision of certified nurse anesthetists by anesthesiologists compared to their supervision by physicians.

The point that we are doing in our reg is not supervision by other physicians, but independently practicing CRNA's who are licensed to do so by the State in which they are practicing.

Mr. BURR. This study suggests that your final rule was incorrect. Is HCFA prepared to go back and pull that final rule proposal?

Mr. BURR. We would always be open to review and adjustment of any of our policies based on evidence like that, absolutely.

Mr. BILIRAKIS. The gentleman's time has expired. Well, a very brief question and a very brief response.

Mr. BURR. Last question, if I could, Mr. Chairman. The physician self-referral laws over which this community has primary jurisdiction were passed by Congress 10 years ago. Earlier you talked through this process that HCFA goes through when implementing a statute.

Notice, common period, final rule and implementation. Could you walk us through that process for self-referral laws Congress passed?

Mr. BILIRAKIS. When you walk through, please do it very briefly.

Mr. HASH. If I may, Mr. Burr, I would like to supply that for the record. I don't have the timeframes at my fingertips. But what I will say here is that clearly we have been delayed. It has taken a very long period of time. We are in the final stages of publishing the final stages of what is called STARK II, which is the second iteration of those referral limitations and we expect to have those out in the fall.

Mr. BURR. So, just for the purposes of all the Members, we don't have any regs?

Mr. HASH. Well, there are regs on the first, but not on the second, not on STARK II.

[The following was received for the record:]

The time line of the self-referral laws Congress passed is as follows:

December 19, 1989: The Omnibus Budget Reconciliation Act of 1989 added section 1877 to the Social Security Act (commonly referred to as Stark I). In general, this law provided that, if a physician (or an immediate family member of a physician) has a financial relationship with a clinical laboratory, unless an exception applies, that physician could not make a referral to the laboratory for the furnishing of clinical laboratory services for which Medicare might otherwise pay. The law also provided that the laboratory could not present or cause to be presented a Medicare claim or bill to any individual, third-party payer, or other entity for clinical laboratory services furnished under the prohibited referral. In addition, the law provided for reporting requirements.

November 5, 1990: The Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) amended certain provisions of section 1877 to clarify definitions and reporting requirements and created one additional exception.

December 3, 1991: We issued an interim final rule with comment period setting forth the reporting requirements.

March 11, 1992: We published a proposed rule setting forth the self-referral prohibition and exceptions, as amended by OBRA 1990 (Stark I) and as they related to referrals for clinical laboratory services.

August 10, 1993: Section 1877 was extensively revised by the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) (commonly known as Stark II) to apply to referrals for 10 additional designated health services. Exceptions were modified and new exceptions were added. Aspects of the referral prohibition were extended to the Medicaid program.

October 23, 1993: The HHS Office of Inspector General (OIG) published a proposed rule that would set forth penalty provisions for violations of the law.

October 31, 1994: The Social Security Act Amendments of 1994 (SSA 1994) amended the list of designated health services and changed the reporting requirements and amended some of the effective dates of the OBRA 1993 provisions.

March 31, 1995: OIG published a final rule with comment period implementing the penalty provisions.

August 14, 1995: We published a final rule with comment period that incorporated into regulations the provisions that relate to the prohibition on physician referrals for clinical laboratory services (Stark I). We incorporated the amendments and exceptions created by OBRA 1993 and the amendments in SSA 1994 that related to clinical laboratory services.

August 5, 1997: The Balanced Budget Act of 1997 (BBA 1997) amended section 1877 to require that the Secretary issue written advisory opinions for the purpose of providing additional formal guidance to outside parties regarding the application of the physician referral provisions. These provisions apply to requests submitted after November 3, 1997 and before August 21, 2000.

January 9, 1998: (1) We published a proposed rule incorporating the statutory provisions enacted through 1994 (Stark II). We also published a final rule with comment period incorporating into regulations specific procedures for issuing advisory opinions, as required by BBA 1997.

We were careful in our proposed regulations to clarify the law and create appropriate flexibility. One of the most important provisions establishes that referrals to an entity with which a physician has a compensation arrangement are generally permissible as long as the compensation is at "fair market value," furthers a legitimate business purpose, and is not tied to the volume or value of physician referrals. This exception goes a long way in simplifying the policy under the law.

We have carefully evaluated the 12,800 comments we received on the proposed regulations and are now working to resolve remaining issues in ways that simplify the regulations while not undermining the law's intent to prevent arrangements that would increase costs to taxpayers and subject beneficiaries to possible harm from unnecessary tests and procedures. We must take great care in translating this important legislation into policy. Important exceptions are needed to protect beneficiaries' access to care, and we must take into account the many detailed financial arrangements in today's health care delivery system.

In the meantime, physicians and other health care entities have by and large made a good faith effort to comply with the law, which is generally self-enforcing. The simple existence of an improper financial relationship is subject to loss of Medicare payment or a civil fine. This creates a powerful incentive to proactively comply with the law through due diligence efforts to avoid financial arrangements that may unethically lead to substantial increases in use of services. The law's preventive nature makes a highly effective contribution to our increasingly successful efforts to protect Medicare and Medicaid program integrity.

Mr. BILIRAKIS. Mr. Strickland, I understand you have a question or two?

Mr. STRICKLAND. Yes, sir. Thank you.

Mr. Hash, I am sitting here feeling almost amazed at myself that I might be saying something positive or defensive about HCFA because you and I have had lots of talks about some of my concerns.

But sometimes I think those of us who sit up here don't accept a reasonable share of the responsibility for the problems that you and others in governmental agencies have.

I just wanted to ask you this question. The proposed budget mark for HCFA is about $220 million, I think, below that requested by the President.

Some of the initiatives or programs that will suffer as a result, I understand, is the nursing home initiative, a reduction of about $35.8 million; Medicare contractor oversight initiative, $42.5 million; Medicare customer service, $143 million; legislative implementation, which enables you to carry out the responsibilities that we gave you under the Balanced Budget Act and so on.

So, given the fact that you do get thousands of letters, and I think everyone on this panel understands what it is like to keep up with correspondence; it is the major headache in my office. Some of my constituents get very frustrated, although we do the best we can answering thousands of letters that are technical in nature and require research, I mean, that is an understandable difficulty that you face.

Would you just take a moment and speak about the lack of resources and whether or not you can do a better job if you have greater resources?

Mr. HASH. Well, I appreciate that question, Mr. Strickland, because resources are an important issue. We are quite distressed about the House mark for the Labor HHS Appropriation for our administrative budget.

It is $220 million below the request of the President and it would eliminate or seriously curtail our initiatives in the nursing home reform area, and our oversight of the Medicare contractors that we have definitely tried to step up.

As you point out, many of our customer service initiatives that we have are at risk, and we are hopeful that as this process moves forward in the Congress that that money will be restored.

Medicare has an administrative budget that is about 2 percent of the money that we actually spend on behalf of beneficiaries. There is no program anywhere like the scope of Medicare that has administrative costs of 2 percent or less.

I don't say that with the sense that that is where it ought to be. I think given the scope of responsibilities that Medicare has, the administrative budget should be significantly larger as a percent of its overall responsibilities.

Just in closing on that point, what people fail to, I think, appreciate often about Medicare is that it is not just about processing claims and paying bills. It is about ensuring the integrity of the process. It is about reviewing the credentials of providers who provide services.

It is about assuring quality of care, not just for Medicare beneficiaries, but for all Americans who use our health care facilities because a Medicare certification of a provider is not just an "it's okay for Medicare." It means it is okay for all Americans.

That is a responsibility that no other health program has and on the kind of budget that we have, I think our ability to do that in an effective and efficient manner is hampered by the lack of resources.

Mr. STRICKLAND. Thank you. I would like to yield to my friend from Ohio my remaining time.

Mr. BROWN. Thank you, Mr. Strickland. Just for clarification, from some of the questions and the comparisons of the HCFA-administered benefit compared with the GOP-insurance based prescription drug plan, just if you would clarify, now my understanding is that Medicare has a single beneficiaries package, a single risk pool, predictable cost-sharing, availability everywhere in the country, no possibility of terminating or changing the plan overnight. Enrollees are not subject to that kind of behavior by the administrator and predictable premiums and all that; is that right?

Mr. HASH. That is absolutely correct.

Mr. BROWN. With an insurance-based prescription drug plan, you can't necessarily count on all those elements; correct?

Mr. HASH. You cannot. We are very concerned about any potential for Medicare beneficiaries not to be able to access affordable prescription drug benefits. Under other plans that do not integrate the prescription drug benefit fully into the Medicare Program, that guarantee is not there, Mr. Brown.

Mr. BROWN. In light of some things also that were said, if we were to privatize Medicare, there were criticism of you from several people, not you personally, but of HCFA in terms of the lack of uni-

formity because of using different administrators in different regions and different states of the country.

If we were to privatize Medicare or pass a private insurance company-based prescription drug benefit, what are the chances that coverage decisions would be uniform across the country then?

Mr. HASH. Well, I think they would, as they do today in the private sector, they would vary according to the decisions of individual plans. Therefore, there would not be uniformity or consistency with what the benefit package would be, what the premiums would be, what the coinsurance or cost sharing would be. All of those are specified as part of the basic Medicare Program and they are guarantees that our beneficiaries can rely on.

Mr. BROWN. So, again, a Medicare-based plan, whether it is prescription drugs or whether it is the Medicare fee-for-service or Medicare as we know it even with the +Choice and all that, in terms of benefit package, the cost-sharing, the availability everywhere in the country, there is a huge contrast between what Medicare offers with prescription drugs if we were to do that and what we would see if we saw an insurance based plan.

Mr. HASH. I agree with that, Mr. Brown.

Mr. NORWOOD. Mr. Strickland, would you yield for just a quick question?

Mr. STRICKLAND. If I have any time, sir.

Mr. BILIRAKIS. You have 44 seconds.

Mr. NORWOOD. Mr. Hash, I was curious about the 1,000 letters a month you receive from Congress. That implies we each write you twice a month or half of us write you four times a month. Is that true?

Mr. HASH. I may have overstated it, but it is in the several hundred a month, I know, and maybe——

Mr. NORWOOD. Mr. Burr, who waited 7 months for a reply surely didn't write every other 6 months waiting for another. If you would check on that I am real curious.

Mr. HASH. Yes, sir, I will.

[The following was received for the record:]

In 1998, we received a total of 12,591 pieces of Congressional correspondence, for an average of more than 1,000 letters per month. In 1999, we received a total of 6,140 pieces of Congressional correspondence, for an average of more than 510 per month. Also, from January 2000 to date, we have been averaging about 510 per month.

Mr. BROWN. Would Mr. Strickland yield to me?

Mr. STRICKLAND. Yes, sir, I will.

Mr. BROWN. My understanding is we all have caseworkers in our districts that write you time after time after time that we don't even necessarily know about. It is not necessarily always a letter that is a policy question. It is more, "can you help us clarify some point" or "would you help our constituents"?

Mr. HASH. That is correct.

Mr. BILIRAKIS. Mr. Upton?

Mr. UPTON. Thank you, Mr. Chairman. Mr. Hash, it is good to see you again. As I have been listening to a number of the questions and the testimony, I wanted to share with you two very frustrating cases that have come across my desk and I think are really

indicative of the frustration that my physicians back home who I meet with fairly often would cite as fairly routine.

One of the examples that my staff and I have been working on for a month now, a physician's office manager in our district called and is trying to figure out what was happening.

It seems that they have been receiving scores of requests for additional information about claims that they had submitted electronically. When they called the carrier they were told that this was a prepayment audit that HCFA had directed the carriers to undertake.

When they asked how long the claim would remain pending, the carrier could give them no estimate. When they asked if interest might be paid on the claim beyond a certain period, 60, 90, who knows how long, days, the carrier told them that HCFA directed them to treat the claims as if they were a claim category in which interest is not paid.

When they checked with the regional HCFA office, that office denied any knowledge of what was going on. This particular office has about 40 percent of their claims being held by the carrier. Despite our efforts to try and get a straight answer, including my staff which had been working on HCFA claims, really, for 20 years, we have been unable to get any type of response at all.

The other sort of normal thing that we have seen, I have spent, earlier this month, a number of hours at one of my physician's clinic and walked through a number of examples that they go through.

Jane, if you could just share a letter. I am going to read parts of it into the record. Actually when I saw down and looked at this case, this is 78 pages long in terms of what they submitted.

They have actually now done what my 7th grade daughter does quite a bit on the computer. She likes to put letters in different colors, yellow, red, and black, to try and highlight.

It starts off by saying that "This claim is now being submitted to you for the ninth time. Six times you have requested a prepayment review on portions. This goes back a good number of months."

In fact, as I indicated, 78 pages of the information that they have submitted, they did receive a letter back since I was there earlier this month, and they asked again for more information, which means now that this is going to be the tenth time in the payment they are trying to seek and trying to clarify the particular procedures that were done.

Now, this clinic is actually pretty familiar to me because this is where I take my kids. I know these physicians. They want to practice medicine. They don't want to go into all the paperwork and everything else and they just want to get paid for a decent day's work. It is unbelievable looking at these types of claims that they are submitting and the rejections back and forth. They really don't seem to be getting anywhere.

I know as I have talked to you in previous years you all process literally 1 billion claims a year. But there is a tremendous frustration with our physician community and with the patients as well, in terms of whether they are covered or not and what goes on, particularly if you deal with Medicare individuals over 65 years old. They just want to get treatment. They want the bills to be paid.

It is a very frustrating number of days in their lives as they try and deal with this.

Going back to Dr. Coburn's questions, Dr. Ganske and Dr. Norwood, somehow we have to come up with a better system than is out there right now because it is just not working.

Our physicians are frustrated beyond belief in terms of the work that they have to do. I wanted to share, particularly, this claim here with you. At the time that I met with Mike I was not aware of this hearing taking place and it was something that we went back and retrieved from my office down the hall this morning.

Mr. HASH. You know, again, I cannot defend this. I think this should have been resolved much earlier. I don't know, obviously, what the facts are here. No matter what the facts are, it shouldn't have gone on for this long.

I can assure you, at least in this particular one and the other one that you mentioned, I am happy to get to the bottom of it quickly and get it resolved one way or another.

On the broader question, you are absolutely right. It is a difficult system, a fee-for-service based system with seven to ten thousand different codes in the physician procedural terminology makes for an extremely difficult system to balance the opportunity for the variation that is required in the care of individual human beings versus the accountability of the program.

In many cases, I think we have not struck the right balance. We are trying to take a number of steps to actually address the failure either of us or our contractors to properly dispose of and dispense with controversies like this in a much more efficient and short timeframe than this lays out here.

I agree with you that experiences like this are what the face of the Medicare Program is to many providers and practitioners.

One of our major goals here is to try to do something in terms of our management and oversight of our contractors in the way that they provide customer service for the provider community as well as the beneficiary community and the way that we invest in educating them to be partners with us rather than adversaries in these matters.

There is no excuse, really for controversy like this to have continued for this period of time.

Mr. UPTON. I am just a layman. I am not a lawyer. I am not a doctor. I dropped chemistry in college. I did very well in high school, but that is a recurring nightmare that the drop did not go into effect and all of a sudden my project is due at the end of the semester.

But it doesn't take very much time to actually go through some of these 78 pages to say, here is the service that was provided. You ought to get paid. The realization by a number of my physicians is that this is the way to delay payment and make money off the interest that is not going to be made.

At the end of the day when in fact something does happen that is positive and the claim is paid, it seems it is fairly often a routine that a number of months later after the case is being closed, it in fact opens up again and they have to go back through the whole case again.

Mr. BILIRAKIS. The gentleman's time has expired. I would love to hear an explanation as to why something like this happens, but, I am going to yield to Mr. Stearns first.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. Hash, in April 1999, HCFA published in the Federal Register a notice announcing a new national coverage process including procedures for seeking review by the new medical coverage advisory community.

In that notice HCFA stated that after a coverage determination was made, HCFA expected, and that is a quote, "to make a payment change effective within 180 calendar days of the first day of the next full calendar quarter that follows the date we issue the national coverage decision."

Help me understand that statement, specifically, tell me, if we approve something today, take me through that statement and see how many days, months, years——

Mr. HASH. What that describes is the process for establishing the payment rate for the covered item or service and the fact that we were committing ourselves to cover it within 6 months after the period that the coverage decision was actually announced.

I think that is intended to be an outside limit because in many cases the payment policy may already be established and it won't take any time to assign an appropriate payment level to the new covered item.

In other cases, if it represents something for which we have no analog, for which we have not paid for anything like it before, we do need to go through a process to develop information about what are other payers paying for this item of service in the private market.

Mr. STEARNS. But you see how complicated this is. It is not just 6 months. There are 180 calendar days. "Of the first day of the next full calendar quarter." What does that mean? "The next full calendar quarters." Why can't you just—I mean once the agency decides to issue a code and affirmatively decides to cover it, why don't you just move quickly and why such bureaucratic language?

But still, take me through the process. You have 180 calendar days of the first day of the next full calendar quarter.

Mr. HASH. For example, if we made a decision today——

Mr. STEARNS. Okay, just take me through that.

Mr. HASH. The next calendar quarter is July 1. I believe that is Saturday. I think that is July 1. That would be the first day of the next calendar quarter. That would be 6 months from then which would be——

Mr. STEARNS. That follows the date we issue the national coverage decision?

Mr. HASH. Right. We issued it today. It would be 6 months from July 1 which would be December 31 or January 1, 2001.

Mr. STEARNS. Okay. Is there any reason why it takes that long?

Mr. HASH. Because it depends on whether or not the item of service that is covered is something that we are already essentially paying for something like it, therefore we can easily establish a payment amount.

If it is something for which we have not been paying for, we have to establish some kind of basis for establishing the price and we

do that by collecting data about what it is being paid for by other payers. Sometimes that takes a period of time.

Mr. STEARNS. Like, you talk about the quarters.

Mr. COBURN. Would the gentleman yield?

Mr. STEARNS. Yes, just 1 second. Let's say it could be more than 6 months. I mean even under your example it is more than 6 months.

But I mean let's say it was in the first quarter of January, February, and March, let's say the first of April you issued it or in the middle of April, then you go the next quarter. That would be three-quarters of a year, right? You would have April, May, and June and then the first of July would start the next quarter.

So, in addition to 6 months, you add another almost 3 months. Then you are talking about 9 months. I mean, it just seems like you wouldn't need that much time to go ahead.

Because you have already affirmatively decided to cover a new technology procedure. So therefore, why can't you just go with it?

Mr. HASH. There are two different questions. One is, is it covered. If the answer to that is yes, how much do we pay for it?

Mr. STEARNS. But don't you decide that at the same time?

Mr. HASH. No. It is not a part of the coverage decision.

Mr. STEARNS. Sure.

Mr. COBURN. If the gentleman would yield. I think there are a couple of other issues. No. 1 is, you won't pay for anything until a CPT code or "J" number has been assigned to it.

Mr. HASH. That is correct.

Mr. COBURN. That is ludicrous and I will give you an example.

Mr. STEARNS. How long does that take?

Mr. COBURN. It takes forever. Let me give you an example. Pap smears that are questionable, a repeat Pap smear with a thin prep pad, it took you all 18 months to approve payment for a thin prep Pap smear, 18 months. They wouldn't pay for it.

So, what happens is, the patient pays for it because we have them sign a deal, this is not a covered service. So the patient has to pay for it.

The question I wanted to ask is: Do you have an incentive system out there for your carriers to not pay or to delay payment or to find more fraud?

Mr. HASH. No, sir, we do not.

Mr. COBURN. There is no incentive at all for a carrier to lessen their payments or to find more fraud.

Mr. HASH. No, sir, they do not.

Mr. STEARNS. Reclaiming my time, but you see what he is saying, you are saying there are two things, you are implementing the procedure and then determining the cost. Give me an example. Are we talking about, as he says, 18 months or a year? I think what you seem to understand here is that you have bureaucratic language and you are not getting with it.

I don't think a corporation today that is trying to earn a profit is going to do this. I am not saying you should make a profit obviously, but I am saying you should expedite this along.

Mr. HASH. The whole purpose of the coverage process that you are referring to from that note was to bind ourselves to specific timeframes because in the past the process, as Dr. Coburn just

pointed out, was very uncertain, took place over a long period of time, and we would view these commitments as you have just read to me, as improvements in the timeliness and responsiveness of the process compared to what it had been in the past.

Mr. STEARNS. Based upon this new published notice in the Federal Register, what have you seen out in the field now? What is the average time?

Mr. HASH. We started using the 90-day process——

Mr. STEARNS. 180?

Mr. HASH. No, no, no. I am back to the coverage process itself. In that notice you are referring to, we said we would do those reviews and make a decision within 90 days. We have been doing that unless there was an issue about additional evidence that had to be submitted. But generally, we have been living up to that 90-day requirement.

With respect to the assignment of a payment or reimbursement level, I don't know exactly what the timeframes have been, but I would be happy to check on them.

Mr. STEARNS. You should know, though. I mean that would be something that——

Mr. HASH. Well, there are a lot of things I should know, Mr. Stearns, but I just don't happen to have that one. But I will try to get for you a list of all the ones we have approved since July and when the payments were established for use by a carrier.

[The following was received for the record:]

Since publishing Medicare's new coverage process in the Federal Register on April 27, 1999, the following pending and completed National Coverage Determinations have been posted on the HCFA web site at http://www.hcfa.gov/quality/8b.htm. National Coverage Decisions (NCDs) can take a number of forms. They can cover or not cover medical items or services, leave coverage decisions of medical items and services subject to regional practice variations to local carriers, or make coverage decisions with limitations. It is just as important for Medicare beneficiaries that NCDs made to not cover items are implemented as swiftly as those made to cover items. Therefore, this list includes all of the NCDs HCFA has published.

1) Augmentative and Alternative Communication (AAC) Devices—On April 26, 2000, HCFA published a NCD classifying AAC devices as durable medical equipment (DME) and therefore eligible for coverage by Medicare carriers. The non-coverage decision on these devices could be found in the Coverage Issues Manual sec. 60-9, which was based on Section 1861(n) of the Social Security Act (the Act) which defines DME. The longstanding policy was based on a determination that AAC devices were "convenience items" and therefore not DME. The Center for Health Plans and Providers (CHPP) decided that AAC devices do fit within the definition of DME. The Office of Clinical Standards and Quality (OCSQ) decided that many factors may weigh into the decision of whether this device would be medically reasonable and necessary for an individual beneficiary. Therefore, effective January 1, 2001 coverage of this piece of DME is at carrier discretion.
2) Autologous Stem Cell Transplantation (AuSCT) for AL Amyloidosis—On January 14, 2000 HCFA published a NCD to not cover AuSCT for AL Amyloidosis because of a paucity of evidence on its effectiveness. This decision is effective October 1, 2000. HCFA received a formal request to examine this treatment for this indication which had not previously been addressed at the national level and was therefore at the discretion of local contractors.
3) Autologous Stem Cell Transplantation (AuSCT) for Multiple Myeloma—On May 31, 2000 HCFA decided to issue a NCD for AuSCT in the treatment of multiple myeloma limited to patient populations shown to derive benefits from the treatment. This NCD is also effective October 1, 2000.
4) Breast Biopsy—On December 7, 1999 HCFA established a national coverage policy for percutaneous image-guided breast biopsy for some non-palpable lesions and left coverage of non-palpable lesions to the discretion of individual carriers.

5) Continuous Subcutaneous Insulin Infusion Pump—On August 26, 1999 HCFA issued a NCD to cover continuous subcutaneous insulin infusion pumps for type I diabetics. This decision was effective for services furnished on or after April 1, 2000.
6) Electrical Stimulation for Fracture Healing—On November 9, 1999 HCFA issued a NCD maintaining a limitation on coverage of electrical bone growth stimulators to long bones, but changes it definition of nonunion fracture from a fracture in which healing ceased for nine months to one where it ceased for three or more months. Effective for services performed on after April 1, 2000.
7) External Counterpulsation Therapy—On November 22, 1999 HCFA amended sec. 35-74 in the Coverage Issues Manual (CIM) to reinforce a previous NCD effective on July 1, 1999. On July 1, 1999 HCFA changed its non-coverage NCD by issuing a NCD to cover this device for patients diagnosed with disabling angina (Class III or Class IV, CCSF score or equivalent classification) and who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention. The November decision, written in response to two separate formal requests on this topic—one to broaden the terminology to include other devices and the other to reconsider the coverage policy and withdraw coverage of this service altogether, changed the wording in the CIM from "Enhanced External Counterpulsation (EECP)" to "External Counterpulsation (ECP)". While EECP was commonly used in the medical field, EECP was a proprietary name and therefore a revision to the original decision was needed to clarify that equivalent devices produced by other manufacturers were also covered.
8) Extracorporeal Immunoadsorption (ECI) Using Protein A Columns for Treatment of Rheumatoid Arthritis—On April 27, 2000 HCFA expanded its coverage of this treatment. Since 1991, the treatment has been covered for only for idiopathic thrombocytopenia purpura (ITP). Recently, the labeling instructions including using this treatment for severe rheumatoid arthritis sufferers. Effective on January 1, 2001, Medicare will cover this treatment for rheumatoid arthritis sufferers who have failed at least three disease-modifying anti-rheumatic drugs.
9) Ferrlecit—On April 20, 2000 HCFA issued a NCD to cover this intravenous iron therapy drug for end stage renal disease (ESRD) patients. Since this is a new drug, no national policy had been in place and therefore coverage of the drug was at the discretion of local carriers. Effective thirty days following issuance of instruction, which is currently in the clearance process.
10) Helicobactor Pylori Testing or Fecal Antigen Assay for Diagnosis of Helicobactor Pylori (H. pylori)—On November 8, 1999 HCFA issued a NCD retaining contractor discretion of this test. The test had been at contractor discretion before HCFA received the formal request to review for national coverage by Meridian Diagnostics, Inc. HCFA believes that leaving this diagnostic test to contractor discretion will encourage technology diffusion at the local level and create an opportunity for stool antigen testing to obtain an appropriate diagnostic foothold.
11) Liver Transplantation— On December 2, 1999 HCFA issued a NCD to remove the exclusion of patients with hepatitis B, but to retain the exclusion of patients with liver cancer in CIM sec. 35-53. This decision was effective on December 10, 1999.
12) Pressure Reducing Therapy (Support Surfaces)—On June 12, 2000 HCFA issued a NCD which modifying CIM sec. 60-19 entitled "Air-Fluidized Bed". Air fluidized bed therapy had been covered with some limitations including a requirement that conservative treatment be used first. The modifying NCD defined conservative treatment. Anticipated effective date is December 2000 when instructions to Durable Medical Equipment Regional Carriers (DMERCs) are issued in the next quarterly bulletin.
13) Prolotherapy for Chronic Low Back Pain—On September 27, 1999 HCFA issued a NCD retaining its national non-coverage policy in CIM sec. 35-13. Since no systems or coding changes were necessary, the policy was effective immediately.
14) Re-Evaluation of Criteria for Medicare Approval of Transplant Centers—On July 26, 2000 HCFA issued a NCD revising the criteria for Medicare Transplant Center Medicare approval. The NCD maintained existing standards for patient selection, management and commitment. Also, the NCD kept the standards for facility plans, survival rates, maintenance of data, organ procurement, laboratory services, and billing. The NCD changed volume criterion to require 12 transplants over a 12-month period for heart and liver transplant centers, and 10 transplants over a 12-month period for lung transplants and eliminated the 2-year minimum experience requirement. Instructions making this policy effective have not yet been issued.

15) Ultrasound Stimulation for Nonunion Fracture Healing—On July 31, 2000 HCFA issued a NCD rescinding its national noncoverage policy on Ultrasonic Osteogenic Stimulators. CIM sec. 35-48 is amended to define osteogenic stimulators and covered indications. Instructions making this policy effective have not yet been issued.

Mr. STEARNS. Thank you, Mr. Chairman.

Mr. BILIRAKIS. All right. We have gone all the way through here. The chair is going to claim the 2 additional minutes because he gave it to the others and didn't take it for himself.

Following up, Ms. Eshoo is not here, but the device problem, I understand that the agency is continuing to insist on a buy brand rather than the category approach to classified devices.

There are numerous problems with the buy brand approach. I think those have already been shared with you. Let me ask you, Michael, is there any precedent in Medicare's history of establishing a payment system based on a brand of technology?

Mr. HASH. Well, I don't think there is, but I think the way we got there is by our reading of the Balanced Budget Refinement Act last December when it was signed into law. It says that, it refers to specific items that were in use after 1996, which is the base rate for the payments.

Mr. Chairman, I didn't get a chance to say this earlier, but we have had long discussions with folks who are interested in the category approach to reviewing and approving these items. We have indicated that we would be willing to talk about a categorization scheme. We think it has pluses and minuses. But we couldn't implement it at the very outset here by August first, which is the implementation date of the outpatient PPS.

But since we are going through, as I indicated earlier, quarterly updates where new technologies are considered and added every quarter, we would over time be able to think about developing a categorization scheme and we are open to having that discussion.

Mr. BILIRAKIS. I understand that industry has offered to sit down with you since December of last year to do just that. They say a system of 8 to 10 device types could be easily developed; is that true?

Mr. HASH. I think they have indicated to us that they want to have such a scheme. We don't actually have such a scheme and in order to put one into place while we are, at the same time, trying to review over 300 applications, we didn't feel that we could do all that and have our payment system in place by this summer, which was the goal which we had established through the statute.

Furthermore, we do believe that our reading of the statute does produce the kind of outcome that we have done. When we were consulting with the Congress when the provision was written, we indicated at that time this was exactly how we would administer it.

Mr. BILIRAKIS. I think it is related to comments that I have made previously and that is a willingness on our part, the Congress. I know sometimes we draw these things up and there are unexpected consequences. If you come back to us and basically say to us, look we kind of agree with you on these categories but we need some changes made.

You know, certainly we would address that. But it hasn't taken place.

By the way, Mr. Oxley, who is not a member of this subcommittee but is a member of the full committee, has two concerns related to HCFA implementation of Section 401 of the Balanced Budget Refinement Act. I am not going to read those to you, but I am going to furnish them to you and request a relative soon type of a response, not 7 months as Mr. Burr experienced.

Mr. HASH. Yes, sir.

Mr. BILIRAKIS. There will be a number of questions in writing which I know, as per usual, you will respond to, hopefully within a short period of time.

I will yield the balance of my time approximately 1½ minutes, to Mr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman. I want to follow up on the issue of audits. Correct me if I am wrong, but when you do audits of physicians or when you have done it at hospitals, you have looked at a limited number and then when you find mistakes where the coding has resulted in higher payment, you extrapolate from that number to the total number of cases and then you want a refund.

Am I not also correct that when you do those audits if you find codes that have been coded lower than normal then you are not taking that into consideration or are you taking that into consideration to balance out the——

Mr. HASH. We are, Dr. Ganske.

Mr. GANSKE. Were you doing that initially or has that been a change?

Mr. HASH. I am not aware that that is a change, but I think that there might have been inconsistent performance by the contractors. We have indicated and redoubled our indications to them that this is a requirement that any claims that are under-coded, that those be adjusted properly to the right code and reimbursement be made or netted out against any overpayments that are determined.

Mr. GANSKE. When did you send out that information to the contractor?

Mr. HASH. I don't have that right at my fingertips but I will get you something that will show you how we addressed that.

Mr. GANSKE. Will that be retroactive to the audits that have been done before?

Mr. HASH. I don't know, Dr. Ganske. I don't know how it is worded. But I do know that it has been our intention that underpayments be netted out against overpayments. It is not just overpayments.

Mr. GANSKE. And that has been your policy all along?

Mr. HASH. I believe it has been our policy.

Mr. GANSKE. So if the contractors were not doing that initially, then the providers that were unfairly hit with not having the positive part counted in should get a refund.

Mr. HASH. I think it should be netted against whatever liability they might have.

Mr. GANSKE. Have you actually put that in writing?

Mr. HASH. I need to review the documentation on that, Dr. Ganske. I don't know right off the top of my head. But I will.

Mr. GANSKE. It should be in writing; shouldn't it?

Mr. BILIRAKIS. Your office can follow up with something on that.

Mr. HASH. I will get you whatever we have on that subject.

[The following was received for the record:]

First, it must be understood that, as a general matter, post-payment audits are not performed randomly, but rather are data driven and are performed when the contractor believes an overpayment exists. In fact, in a recent Program Memorandum (Transmittal AB-0072), HCFA reminded Medicare contractors of the steps that must be taken for the efficient and effective use of medical review. For example, the Memorandum stresses that the decision to conduct medical review should be "data-driven," and that potential problems should be validated by conducting "probe" reviews (i.e., reviewing a limited number of claims). Finally, post payment audits are only to be performed when there is a major level of concern about overpayments. Thus, Medicare contractors take into account whether a provider has been underpaid in their initial decision regarding whether to conduct post-payment audits.

Second, when contractors do perform post-payment audit, they take into account both underpayment and overpayments. Written instructions in March 1999 were issued stating that in calculating overpayment using a statistically valid random sample, contractors should offset underpayment against overpayments. Such instructions were not retroactive; however, it has always been HCFA's policy to pay it right, which has implications for overpayments as well as underpayment.

Mr. BILIRAKIS. Well, we are going to let you go now, Mr. Hash. I honestly don't think that HCFA has been bashed. You certainly haven't been bashed. You experience the frustration that is felt and the reason why I wanted to extend the time is because we have three medical providers on this committee and they are the real world with the experiences out there. Ms. Capps is a nurse. I certainly didn't mean to slight her. She is a provider, too.

So, this is why I wanted to extend more time. It took a little longer. I apologize to the second panel for their being delayed as long as they have been, but it is important that we go into this.

In the past we have met with you sort of sitting around a table and giving people an opportunity to raise some of their frustrations, some of their problems. You have responded and hopefully, maybe we can do that again sometime.

I would have like to have seen this hearing devoted just to you, quite frankly.

Mr. HASH. I want to say to you, Mr. Chairman, I do appreciate the spirit in which people have entered into this discussion. I do appreciate the frustrations that are expressed here on behalf of others. I know they are real because I have been out there myself.

I do think if we can command the proper amount of resources that we can continue to work with the provider community and with you all, that together we can continue to ensure that Medicare serves the next generation of beneficiaries.

I appreciate the constructive way in which you have conducted this hearing.

Mr. BILIRAKIS. Michael, you were a part of this community for so many years as counsel. You know us and we know you. There shouldn't be any hesitation on your part to say to the committee, hey, we need some changes made in order to be able to do a better job.

Mr. HASH. Yes, sir.

Mr. BILIRAKIS. Again, part of my frustration is that that has not taken place.

Mr. HASH. I understand. Thank you, Mr. Chairman.

Mr. BILIRAKIS. Panel two consists of Dr. Robert R. Waller, Chairman of the Healthcare Leadership Council; Mr. Dave Fleming, Group Senior Vice President, Diagnostics Products and Genetics, Genzyme Corporation on behalf of advaMED here in Washington, DC; Mr. Michael F. Mangano, Principal Deputy Inspector General, Office of the Inspector General, Department of HHS; Dr. Yank Coble from Jacksonville, Florida, welcome to Washington, Dr. Coble, a member of the Board of Directors of the American Medical Association, and Ms. Vicki Gottlich, attorney, Center for Medicare Advocacy.

Welcome. Ladies and Gentlemen, your written statements are a part of the record. I will set the clock at 5 minutes. Hopefully, you can stay within that period of time. Obviously, if you go over a few seconds, no problem, but we would prefer that you sort of complement and supplement your written statement as much as possible, if you would do it.

Dr. Waller, we will start off with you, sir.

STATEMENTS OF ROBERT R. WALLER, CHAIRMAN, HEALTHCARE LEADERSHIP COUNCIL; DAVE FLEMING, GROUP SENIOR VICE PRESIDENT, DIAGNOSTIC PRODUCTS AND GENETICS, GENZYME CORPORATION ON BEHALF OF ADVAMED; MICHAEL F. MANGANO, PRINCIPAL DEPUTY INSPECTOR GENERAL, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; YANK COBLE, BOARD OF DIRECTORS, AMERICAN MEDICAL ASSOCIATION; AND VICKI GOTTLICH, CENTER FOR MEDICARE ADVOCACY AND THE NATIONAL ACADEMY OF ELDER LAW ATTORNEYS

Mr. WALLER. Thank you. Good afternoon, Mr. Bilirakis, Mr. Brown and members of the committee. Thank you for this opportunity.

As you have heard, Medicare is one of our great social programs in this nation. I think our government deserves more thanks than it often receives for its commitment to our nation's health.

Those who administer Medicare, Nancy-Ann Min De Parle, Mike Hash, Dr. Bob Berenson, and others are dedicated, talented people. But the system is broken. All of us can share responsibility for where we are today. Seven administrations, 18 Congresses, all of us in the health care sector and our patients.

The bottom line for the Health Care Leadership Council is that we just can't adequately manage our current system so we need to change it. The drivers for change are overwhelming You have heard them, issues of quality and cost and access and solvency top everyone's list.

But complexity has to be added to the chief drivers. Complexity is staggering. According to a recent survey that we have done, complexity is a No. 1 issue for the beneficiaries. A prime indicator of the complexity is the 110,000 pages of Medicare rules and regulations.

This is 1 year's worth from the Federal Register on the table. We are spending precious time counting the number of pages of rules and regulations that we don't have or that we do have and how

many rules and regulations we have now has kind of taken on a life of its own.

The consequences of complexity are enormous. Let me mention three quickly. Complexity stifles innovation. The goal that we all have is to constantly improve care and not to achieve a defined regulatory standard.

Health care is constantly improving, such as the genome project. If you place a regulatory stake in the ground and define what quality is today, tomorrow that quality may be in the wrong place.

Second, dealing with the labyrinth set of rules and regulations does create honest differences of opinion in interpretation of those regulations and breeds and stakes. I am concerned that the public has been led to believe that the Medicare system is riddled with fraud, when in reality complexity so often is the root of the problem.

We have heard about the need to have zero tolerance for real fraud, but differences in interpretation of rules and honest mistakes are not fraud.

Third, complexity is stealing time from patient care. Dr. Coburn is exactly right. A recent survey found that 22 percent of our physician and office staff time is devoted to compliance with Medicare regulations and it also noted that processing costs with Medicare claims are about 26 percent higher than the costs associated with private claims. We need less paper and more care.

A few examples of complexity: Completing claim forms are nightmarish for the physician and the patient. Denied claims can take up to several years to complete, as you have heard. Services covered in one location of care are not covered in another location of care. The process for seeking new treatments is extraordinarily lengthy. Insurance piecemeal with multiple products.

This is difficult for patients, difficult for providers, and it leaves the system vulnerable to honest errors and true fraud.

At the top of our list, Dr. Coburn's concern, having to document what patients don't have. I practiced medicine at the Mayo Clinic for 30 years, was President of the Mayo Foundation for 11 years up until last year. Our colleagues and the members of the Healthcare Leadership Council will tell you that working with private payers, we work with them as partners.

The private payer does not require us to document the number of body systems that we must examine to bill for a visit or whether the supervising physician must be in the same room when a nurse tests a patient's pacemaker. The record has indeed become less of a record of care and more of a legal and a billing and a coding document, as Dr. Coburn said.

So, in short, Medicare in its current structure with continued price controls, ratcheting down of payments to providers and plans, yes, micromanagement and a piecemeal approach to coverage just will not work.

We have noted the efforts to assist providers conducting town meetings, providing toll-free lines, advisory committees and yet developing more volumes of guidelines. These are additional manifestations of a regulatory system with an increasing number of negative consequences for patients.

There are 55 chief executives of the Healthcare Leadership Council who represent all health care sectors and they believe that the current system needs to be uprooted and replaced with a system where there is more choice, similar to what Federal employees, including Members of Congress, and many employed Americans now have, more competition, more innovation and shifting the private, public partnership that we now have more toward the private sector.

I will just sum up by saying we know it is going to take time to achieve comprehensive reform. We do have some interim suggestions that I hope the committee will find helpful.

First, please stabilize the current Medicare Program. There is a financial crisis for providers and plans and it must be addressed.

Second, appoint a Medicare board external to the Health Care Financing Administration. This will be a key element to encourage competition, ensure more flexibility and less regulation.

Third, improve the collaboration among the agencies enforcing the Medicare regulations. The Office of the Inspector General provides reduced penalties for voluntary disclosure of billing errors. The Department of Justice does not. If it is an error, why should there be any penalties at all?

Fourth, we need a better system to account for the costs associated with more regulations. One example, HHS estimated that costs to implement medical records privacy regulations would cost $3.8 billion over 5 years.

An independent organization estimates costs to be over $40 billion over 5 years. Somehow we need to be on the same page. Medicare is a great social program. It has been structured for a different time and a different science.

The Healthcare Leadership Council looks forward to working with the committee toward comprehensive reform, which we hope will happen very, very soon. Thank you.

[The prepared statement of Robert R. Waller follows:]

PREPARED STATEMENT OF ROBERT R. WALLER, PRESIDENT EMERITUS, MAYO FOUNDATION AND CHAIRMAN, THE HEALTHCARE LEADERSHIP COUNCIL

INTRODUCTION

Good morning Mr. Bilirakis, Mr. Brown and members of the sub-committee. I want to thank you for your invitation to appear here today to convey the views of the Healthcare Leadership Council on the very compelling issue of how the complexity of the Medicare program hinders patient care. I would also like to thank this committee for the extensive leadership and dedication to the Medicare program you have provided over the past several years.

The Healthcare Leadership Council (HLC) represents a comprehensive spectrum of innovators in the health care sector. Because of this broad representation, what I convey to you today can be considered a unified position of a variety of the nation's most respected leaders in the delivery of health care services and products.

The HLC has been committed, since its inception, to advancing a health care system that values innovation and provides affordable, high-quality health care in a patient-centered environment. Beneficiaries of the Medicare program deserve no less. We believe that Medicare is a valuable social program. Medicare has broadly impacted the health and financial security of all Americans, young and old. It provides health coverage to almost one of every ten Americans. And it relieves millions of the elderly's children from what could be catastrophic medical expenses.

Today's Medicare, however, has some very real problems that must be squarely faced. Under Medicare's current structure, the federal government has been unable to manage Medicare efficiently. The program is highly regulatory and inflexible, with over a hundred thousand pages of regulations, rules, manuals, instructions, let-

ters, alerts, notices, etcetera. Carriers and intermediaries apply rules differently in different locations. And there are often inconsistencies among these many rules.

Of late, trust fund longevity has been the driving force behind calls for Medicare reform. But Medicare insolvency, as critical as it is, is not the most immediate danger facing Medicare beneficiaries. While insolvency could rob beneficiaries of high quality, innovative health care in the near future, the inefficiencies of the Medicare program are robbing beneficiaries now.

No single source is to blame for the inefficiencies and complexity of the current Medicare program. The massive amount of regulation for this program has evolved at the hands of seven administrations, and 18 Congresses. And those of us in the health care system share responsibility as well. I would even compliment those who regulate this program—in both the Congress and in the Health Care Financing Administration. They are good and talented people. But it is beyond the power of the most powerful policy makers to make substantial improvements to the existing Medicare program. *The system as a whole needs to be uprooted, and replaced with a private, value-based, competitive system. Under such a system, plans and providers would compete with one another to offer—not just the highest quality, most innovative care—but also the most user-friendly delivery of care.*

In my comments today I would like to discuss the patient consequences of our complex Medicare program. I will provide some examples of where the Medicare program is characteristically burdensome for both consumers and providers. And I will outline HLC's vision for an efficiently run Medicare program.

CONSEQUENCES OF TODAY'S COMPLEX SYSTEM

The inefficiencies within the Medicare program adversely affect its beneficiaries on many fronts.

First, Medicare's complexity stifles innovation. Medicare cheats beneficiaries from being able to receive the best care achievable when its regulations set inflexible standards of care. On virtually a daily basis, our nation's health system makes incredible advances in the diagnosis and treatment of illnesses, and on new approaches to optimizing good health. These advances are improving the quality of health care at a pace far more rapid than the legislative or regulatory process can maintain. Quality improvement is a continuous process that must be woven into the fabric of how providers of care think, act, and feel. The goal should be to constantly improve patient care, not to achieve a defined regulatory standard. Regulating quality essentially freezes in place today's best practice—which may be a mediocre practice less than a year from now.

Second, complex Medicare regulations contribute greatly to a false image of a system plagued with fraud and abuse. Let me begin this part of the discussion by stating clearly that the Healthcare Leadership Council has zero tolerance for true fraud and abuse. True fraud and abuse in our health care system undermines quality, threatens patients' trust, should not be tolerated, and must be eradicated.

But the public's confidence in the nation's health care system has been eroded by headlines of health care fraud investigations that are not always the result of true, intentional fraud. Many have been led to believe that Medicare is riddled with fraud when, in actuality, complexity is more often the root of fraud investigations. Accusations of fraud are most frequently the result of honest mistakes and differences in interpretation in dealing with a labyrinthian set of confusing and conflicting regulations. This complexity actually undermines compliance.

Most of those on this panel are probably aware that Medicare grew by only 1.5 percent in 1998 and by a negative 1 percent in 1999—the lowest rate of growth in Medicare's history. This reduced growth rate has been attributed in part to cuts by the Balanced Budget Act of 1997, and to reduced fraud and abuse. But do you know that this remarkably slow grow is largely due—not to the actual reduction of fraud—but to the tremendous fear of false accusations of fraud? Recent evidence shows that health care organizations have been going to great expense to avoid the Department of Justice's overzealous use of the False Claims Act by undercoding for their service in order to avoid any possibility of false accusations of fraud.

February, 2000 testimony from the Congressional Budget Office included an analysis of changes in hospital billing patterns and their impact—the analysis noted that, for example, hospitals have been down-coding "simple pneumonia" to "respiratory infection" at a far greater rate than ever before. However, the Medicare Payment Advisory Commission pointed out in its 2000 annual report to Congress that CBO did not analyze the clinical appropriateness of these coding decreases. In fact, Gail Wilensky, Chairman of the Medicare Payment Advisory Commission was recently quoted as saying that billing Medicare for less than a provider is entitled

is a serious problem. She added that "You don't hear the OIG or the Department of Justice worrying about whether we are underpaying".

Third, today's complex and burdensome Medicare system saps time and financial resources. Time and money spent by providers on extensive documentation, poring through compliance guidelines, and hiring compliance experts, could be used more productively in providing patient care or developing innovations to improve patient care. A more efficiently run Medicare could perhaps even return to the beneficiary some savings to offset certain medical expenses and other out-of-pocket costs. A recent survey of the Association of American Physicians and Surgeons revealed that 22 percent of physician and office staff time is devoted to compliance with Medicare regulations. In addition, they found that the processing costs associated with Medicare claims are 26 percent higher than the costs associated with private claims.

EXAMPLES OF COMPLEXITY WITHIN THE PROGRAM

Features of the Medicare program that consume providers' time and resources and cause confusion for Medicare beneficiaries include the following:

Medicare's many complex coding and documentation rules make completing the claim form and ensuring appropriate coding extremely burdensome and time-consuming. For example, drugs must be coded with a Medicare-specific code, and the provider must adjust billed quantities to comply with the code description. Private health plans, on the other hand, use national drug codes assigned to all drugs approved by the FDA.

In addition, Medicare's documentation requirements lead to redundant and inefficient documentation practices. For example, physicians must write all notes regarding patient assessment, regardless of whether a registered nurse under his supervision wrote identical notes at an earlier point in the day that concur with the physician's view.

As another example, I have attached to my testimony, a seven page guideline describing the examination and documentation requirements for billing under CPT code 99215—one of approximately 10,000 CPT codes. You can see from this document how extensively the Medicare program prescribes the activities that must take place within the patient examining room in order to bill under just this one code. For example, billing for a "complete review of systems" requires "at least ten organ systems to be reviewed". Those systems with positive or pertinent negative responses must be individually documented. For the remaining systems, a notation indicating all other systems are negative is permissible. In the absence of such a notation, at least ten systems must be individually documented.

Medicare's extensive coverage process for new items and services can leave beneficiaries behind the curve of advancements in health technology. The administrative process used for modifying benefits and for determining whether certain medical treatments or procedures merit coverage under Medicare is extraordinally complex, lengthy, and sometimes irrational—resulting in the delay or denial of lifesaving treatments. For example, even though scientific evidence had shown for sometime that the outcomes for Hepatitis B liver transplants were comparable to the outcomes of liver transplants made necessary by other primary indications, Medicare did not begin covering these transplants until very recently. In 1999, before Medicare began covering Hepatitis B liver transplants, a survey by the American Liver Foundation found that 99 private insurance companies, as well as the Department of Defense, reimbursed for Hepatitis B transplants. The survey also showed that most of the largest liver transplant centers indicated that Medicare was the only carrier that did not reimburse for these transplants.

Medicare's standards of care prescribed in regulation are often inflexible and often nonsensical. Efforts to protect the program from fraud have led to tedious rules that reduce the quality of a patient's interface with the medical system. For example, Medicare will not reimburse for physician visits and/or diagnostic tests that occur more than once per day per patient. As a result, patient care may be compromised, patients are inconvenienced, providers are unable to run confirming or clarifying diagnostic tests, and the course of care is disrupted.

This is especially a concern of Medicare patients of the Mayo clinic who often travel long distances to use our medical facilities for a series of diagnostic tests and treatments during the minimum number of days possible. Because of Medicare's prohibition against payment for two separate evaluation and management services occurring on the same day, we are faced with the choice of either not being paid or requiring patients to prolong their stay and then incur unnecessary hospital costs or costs for lodging, meals and other expenses. This rule is also a problem for Medicare beneficiaries in rural areas who must travel to a distant urban area for similar tests and treatment.

Medicare beneficiaries and providers constantly wrestle with a piecemeal approach to insurance. Beneficiaries must piece together multiple health insurance products—including Medicare, Medicaid wrap-arounds, Medigap, and retirement wrap-arounds—like a jigsaw puzzle, in order to be comprehensively covered. In addition, their providers must deal with the multitude of instructions and claims paperwork associated with this piecemeal coverage. This hybrid of uncoordinated care increases the system's vulnerability to billing errors as well as true fraud and abuse.

Medicare has inconsistent coverage policies based on the specific site of care. For example, infusion services are covered in the hospital, but not in the home setting. As another example, a rule proposed in 1997—yet still not finalized—details physician supervision requirements for numerous office procedures. The regulation actually dictates during which procedures a physician must supervise from within the examining room and which procedures the physician can supervise from within the "office suite" but not necessarily within the examining room.

Such site of care standards are unnecessary inconsistencies that take discretion away from providers, reduce the quality of care for beneficiaries, and simply lengthen the long check list of rules that providers must remain wary of when treating beneficiaries.

Medicare's very lengthy appeals process can result in long waits for needed care or for payments for services rendered long ago. When Medicare carriers deny claims, there are several tiers of review, the highest of which—review by an Administrative Law Judge—can take up to four years to complete. In the meantime, either the beneficiary is denied this care, or a provider is denied payment.

HLC'S VISION FOR EFFICIENCY

HLC's vision for administering Medicare in this century is a management model that is lean, efficient, independent, and able to adapt quickly to innovation. We see a Medicare program that will not steal time from patient care, will not be a hybrid of uncoordinated health care programs, and will not have inflated costs because of burdensome micro-management and heavy government regulation. We believe strongly in the need to provide seamless, integrated care for the total care of the patient.

This model already is working well for some 59 million Americans in large employer plans and the nine million people in the Federal Employee Health Benefits Plan (FEHBP). Under FEHBP, the government's micro-management and mandating of benefits is kept to a minimum, consumers have better benefits, lower out-of-pocket costs, more choice, and higher quality care. If used for Medicare, this model would allow the market to respond to changing beneficiary needs with a variety of products, keeping pace with advances in health care. Medicare beneficiaries deserve these quality improvements.

The Mayo Clinic, like many members of the HLC, works with many private insurance companies and payers. We deal with them as partners, through a process of negotiations, establishing goals for quality, cost, and patient satisfaction, and monitoring the results. These insurance companies do not tell us how to document the number of body systems we must examine to bill for a visit, or whether the supervising physician must be in the same room when a nurse tests a patient's pacemaker. The more efficient Medicare we envision would not try to micromanage virtually every aspect of the care patients receive, but would allow providers and plans to compete in a marketplace on the basis of quality, cost, and efficiency, holding us accountable for the care we provide.

Medicare must embrace the innovations in health care delivery, benefit design, and cost management techniques that have occurred in the private sector in order to best serve its beneficiaries. A Medicare system that is run efficiently will be dedicating its time to patient care, not to the administration of regulations. And such a system will be free of the inflated costs that are associated with inflexibility and burdensome micro-management.

THE INTERIM

As I said earlier in my testimony, I do not believe there is a way to fix the existing Medicare program without starting completely from scratch, not that there haven't been valiant efforts to do so. In fact I would like specifically to complement Dr. Robert Berenson who has traveled to the Mayo Clinic to listen to our concerns and to try to correct some of the problems we face. And earlier in this hearing, we heard from Mike Hash of HCFA about some impressive efforts underway to try to help providers and plans navigate the complex maze of this program.

But I believe that these efforts to assist and educate providers, to provide toll free lines, to conduct town meetings, to develop more volumes of guidelines are just addi-

tional manifestations of a regulatory system gone awry. The additional resources required of HCFA to develop these various guidance tools, and the resources required of providers to take advantage of them *are misdirected resources.*

I do, however, recognize the realities of the time and political process necessary to change a government program of this magnitude and importance. So I would like to mention a few things that the HLC believes would be helpful in the interim.

Our most urgent suggestion is for the Congress and the Administration to work together to financially stabilize the existing Medicare program. While the Medicare's complexity demands ever-increasing resources of health care providers and plans, the overseers of the program have carved away at Medicare reimbursements substantially over the past several years. As a result of the Balanced Budget Act cuts, virtually all Medicare providers groups— Hospitals, home health agencies, skilled nursing facilities, and Medicare+Choice plans—are experiencing severe and ongoing funding shortages. Decreasing payments in conjunction with increasing regulatory and other administrative burden has to eventually prove to be a losing combination for beneficiary care.

Second, we would propose the development of a Medicare management board external to HCFA with authority to adapt to changing health care practices without Congressional activity and HCFA micromanagement, reducing the heavily regulated environment of the current Medicare program.

Third, we suggest an improvement in the collaboration of the agencies involved in the regulation and enforcement of the Medicare program, namely the Health Care Financing Administration, the HHS Office of Inspector General, and the Department of Justice, including the U.S. Attorneys. There is a growing multi-layered network of investigators and prosecutors working through all of these agencies who have conflicting interpretations of Medicare regulations as well as conflicting enforcement programs. For example, the Office of Inspector General has notified Medicare providers that voluntarily disclosing billing errors found within their organizations will result in reduced penalties. However, many organizations are reluctant to come forward with found billing errors because the Department of Justice treats such disclosures the same as if the DOJ had discovered a truly fraudulent cover-up.

To help facilitate better coordination and education among these agencies and the provider community, in 1998, the Healthcare Leadership Council formed our Industry and Government Partnership for Accountability Task Force, which consists of organizations representing every segment of the health care system. Sectors represented include: hospitals, medical clinics, health maintenance organizations, pharmaceutical companies and medical device manufacturers.

To date, we have had several dialogues with these agencies regarding the intricacies of complying with Medicare regulations. The Industry and Government Partnership for Accountability plans to continue to undertake a significant effort to educate opinion leaders and top government officials and to engage in a constructive efforts to resolve this debate.

We believe that formalization of such a partnership to ensure clarification and consistency in the enforcement of Medicare rules would help to move the current system away from a model based on confrontation and litigation and toward a model based on education and remediation.

And finally, we believe that a more formalized system of regulatory accountability within Medicare could help to decrease the growth of the regulatory burden and compliance costs on providers and patients. Currently, cost/benefit analyses of regulations are only loosely required by an executive order that gives agencies great discretion in determining whether a cost benefit analysis is necessary and how that cost is estimated.

A recent example of controversy in this regard arose around the DHHS's cost estimate for compliance with the recently issued rule on medical records privacy.

While HHS estimated that complying with this new regulation would cost the industry $3.8 billion over the next 5 years, a reputable independent analysis determined that the cost would be over $40 billion over the same period.

Possible alternatives to the existing informal requirements for estimating compliance costs include (1) requiring that the cost of a regulation be conducted by an entity other than the agency developing the regulation, (2) legislating more formalized requirements and guidelines for conducting the cost analysis, and/or (3) requiring the inclusion of how the cost of compliance could materially impact patient care. These alternatives could help to instill greater awareness of the consequence of over-regulation.

CONCLUSION

Today's Medicare was built for another science in another time. The inefficiencies and complexities of this program are such that Medicare beneficiaries are stuck in an outmoded health care program that is capable of delivering, and needs to deliver, so much more. The Healthcare Leadership Council stands ready to help this committee work toward assuring that, in the near future, Medicare beneficiaries are able to take advantage of the full potential of our health care system.

Mr. BILIRAKIS. Thank you, Doctor.

Mr. Fleming?

STATEMENT OF DAVE FLEMING

Mr. FLEMING. Thank you, Mr. Chairman and other members of the committee. I am Group Senior Vice President of Genzyme Corporation and Chairman of the AdvaMED Board Committee on Payment and Health Care Delivery. AdvaMED is the Advanced Medical Technology Association, formerly known as HIMA.

The new name reflects more clearly the industry's central role as a source of medical innovation, research and medical technology.

Mr. Chairman, I am here today to talk about one subject, which many of you on the subcommittee have raised this morning. That is timely patient access to quality health care.

For the past 35 years, Medicare has provided life-saving and life enhancing technologies to millions of Medicare patients. In that sense, Medicare has been a blessing.

Today, though, Medicare processes for improving and paying for new medical technologies are not keeping pace with innovation.

I would like to answer the question asked by Mr. Stearns and in fact, after FDA review, the approval process going through HCFA takes another 4½ years or longer to go through the process and reach the patients. So, again, 4½ years after FDA review.

As you can see from the chart that would be to your right, it lays out the process and again, if you start from the left you have FDA approval. This is something that the Commerce Committee helped reform in 1997, but the rest of the chart refers to HCFA.

If you disentangle and lay the HCFA process end to end, you go through coverage coding and payment process. Ms. Eshoo asked this morning about the first part, the coverage part, where HCFA decides whether to include a new technology in the Medicare payments package.

I do compliment the agency on opening up the coverage process, on making it more transparent, but to clarify, the agency has 90 days to make an initial assessment, not the final coverage decision.

After that time, after the first 90 days, there are no time limits. HCFA can refer the decision to MCAC or to another outside technical assessor which guarantees delays, as mentioned earlier, of 6 months to several years.

So, the coverage decision process in my mind takes anywhere from 12 to 36 months.

The next step is coding, as has been mentioned. New technologies are given a 6 or 5-digit code which providers use when they bill for the service. The coding process in itself takes anywhere from 15 to 24 months. So that is added on to the coverage. Again, payment is not made until you have a code, as has been mentioned by the committee.

The final step involves determining the appropriate payment level, which can take another 2 years on up. So, I want to make the point that medical technologies have to go through this complex, approximately 4½ year HCFA approval process and they usually do not reach the Medicare patients until after the process is done. This is why Medicare needs reform.

Let me cite one example which is on the chart to your left. It involves coronary stents, also mentioned earlier by Ms. Eshoo. This is a revolutionary device that is inserted into the coronary artery during angioplasty to reduce the narrowing and facilitate normal blood flow.

As the chart shows, the medical device manufacturer first requested the unique code in 1990. But HCFA did not approve the new code until 1995, 5 years later. Once the code was approved, it took another 2 years from 1995 to 1997 to set direct reimbursement levels for the stent.

Now, here is the ramifications of that: FDA had approved the product in 1994, but through the time period until 1997, hospitals received $3,000 to $5,000 below per procedure what it cost them to provide the breakthrough technology, the therapy.

So, here is the impact on patient access. During that time when HCFA reimbursed hospitals at the low level, only five to 25 percent of the eligible Medicare patients received the technology. But once adequate payment was finally approved in 1997, patient access improved up to a level of 75 to 80 percent of eligible patients.

So, stepping back a minute, Mr. Chairman, the case study shows a 7-year process from the time the code was requested, and that is, I believe, a virtual eternity in the life of device innovation, which generally takes about 2 years.

More importantly, think of it from the patient perspective. Imagine being that Medicare patient awaiting HCFA's action and not having availability to this life sustaining technology.

So, I think Mr. Chairman, examples like the coronary stent are examples that the system is in serious need of reform. I have a couple of recommendations to provide in addition to those.

Mr. BILIRAKIS. Do so very briefly, if you would.

Mr. FLEMING. First, Medicare must place top priority on streamlining its systems to dramatically shorten the overall 4½ year process.

Second, HCFA should institute reforms that encourage rapid assimilation of new technologies into the Medicare beneficiary plan.

Third, HCFA should update all of the payment systems more frequently, at least annually, to reflect changes in medical technology.

The last point is that we also urge the subcommittee to throw its support behind H.R. 4935, the Medicare Patient Access to Technology Act of 2000. This bill, of course, was introduced by Representative Jim Ramstad and Representative Karen Thurman and is co-sponsored in fact by several members of the subcommittee. I think we view this legislation as critical to digging into the nuts and bolts that we have been talking about all morning.

It really represents a very important down payment on the larger effort to modernize HCFA. Thank you very much, Mr. Chairman.

[The prepared statement of Dave Fleming follows:]

PREPARED STATEMENT OF DAVE FLEMING ON BEHALF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

INTRODUCTION

AdvaMed is pleased to submit this statement as the Subcommittee examines HCFA's management of the Medicare program. AdvaMed, the Advanced Medical Technology Association, was formerly known as HIMA, the Health Industry Manufacturers Association.

Before we begin our remarks, we would like to provide some background on our industry and whom AdvaMed represents.

AdvaMed is the largest medical technology trade association in the world, representing more than 800 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $68 billion of health care technology products purchased annually in the U.S. and nearly 50 percent of the $159 billion purchased annually around the world.

This new name reflects our industry's central role as a source of medical innovation, research, and advances in therapies, diagnostics, and health information technology. This change does not represent a change of role or mission; merely a clearer reflection of those functions.

ROLE OF MEDICARE

Mr. Chairman, Medicare has accomplished a tremendous amount in improving the quality of medical care for beneficiaries over the past 35 years. Medicare has been a blessing. Millions upon millions of elderly and disabled Americans have regained their health, improved the quality of their lives, and lived longer and more productive lives thanks to Medicare.

We also believe we owe a debt of gratitude to the many individuals who have served in the public sector, administering Medicare over that period—and especially those who serve at HCFA today. These individuals deserve special recognition as they are confronted with the infinitely complex tasks of seeing to it that Medicare's 39 million beneficiaries gain prompt access to the highest-quality care, at a time of severe budget constraint.

Despite the hard work of these individuals and the continuing efforts of this Committee and Congress to oversee the activities of the agency, we see an agency unable to keep up with the pace of new medical technology.

As a result, patients are not gaining prompt access to the medical technologies they need and deserve—access that was the very purpose of Medicare in the first place.

Today, we will outline some of the Medicare system's shortcomings. Then we will turn to what we believe are some reasonable solutions in addressing this problem.

COVERAGE, CODING, AND PAYMENT

Before we provide you with a review of recent key issues on how HCFA deals with medical technology, we would like to define some of the key terms that are used to describe Medicare policies on medical technology. Specifically, we refer to "coverage," "coding," and "payment."

Coverage. As you know, Mr. Chairman, once products are reviewed and cleared by the Food and Drug Administration, they must undergo Medicare review to determine if they will be included in the portfolio of services Medicare makes available to its beneficiaries. This is commonly referred to as coverage. It usually occurs routinely as local Medicare contractors process bills from doctors and other providers. But some technologies undergo full-blown national coverage review, which is a complex evaluation of the benefits of a technology—similar to a pre-market evaluation done by the FDA.

Coding. As Members of this Subcommittee are aware, this is just one step in obtaining reimbursement for a new technology. To be covered by Medicare, either locally or nationally, new medical technologies must be assigned what is known as a procedure code. These codes are comprised usually of five or six digits, often a combination of letters and numbers, and identify literally thousands of medical treatments and procedures. Providers use these procedure codes when they submit bills to Medicare and private insurance companies. Virtually all medical products must either fit into existing codes or, if they are unique or breakthrough products, they must have a new code of their own.

Payment. Once a new technology or medical procedure has a code, then the final stage is to determine an appropriate payment level, or Medicare price, for the product. As you are aware, this is accomplished by folding the new technology or procedure into Medicare's various payment systems, each of which has its own complex set of rules governing how technology is treated. These systems range from the Re-

source Based Relative Value Scale, which is a physician fee schedule, to DRGs in the inpatient setting, to the new Ambulatory Payment Classifications (APCs) for the soon-to-be-implemented outpatient payment system.

This Subcommittee is well aware that each of these payment systems is extremely complicated; each has many moving parts. If any one of those parts is not working optimally, access to new technologies for patients and medical professionals will be slowed or even stopped outright. That's because coverage, coding, and payment systems interact with one another. It's not enough to be just covered, or just coded, or even just paid. You need all of these elements to be present and to be operating properly to ensure a prompt and appropriate reimbursement level that permits appropriate access.

Now we would like to introduce the reality that we, as manufacturers, face—and that must ultimately be borne by patients and providers as well. HCFA's systems of coverage, coding, and payment—the systems we just described—are not working well. In many cases, they are slow; they are inefficient; they contain inappropriate incentives; and they are inordinately complex. That does not suggest they do not work; it suggests that they simply do not work well.

For example, the entire process can take four years or more to complete. That includes the one to three years it can take to obtain a coverage decision; the 15 months to two years it may take to secure a code; and the two years it can take to secure an appropriate payment level for a technology. We have attached a chart with this statement that illustrates the times associated with these review processes, as well as several other charts and case studies focusing on particular medical technologies.

Keep in mind that these HCFA processes take place after FDA review, which itself might be a year or so. And that they take place after the time it takes to develop a product, which can consume anywhere from two to six years, prior to FDA review.

We offer this context, Mr. Chairman, because we believe it is critical in understanding HCFA's current performance in reviewing and adopting medical technology in Medicare. This Committee deserves enormous credit for its leadership role in reforming the Food and Drug Administration. But we want to stress that, as far as ensuring access to new technology for Medicare beneficiaries, the goals of FDA reform are often thwarted by HCFA's coverage, coding, and payment policies.

And the effects of this are clear: *Patients, and the medical professionals who treat them, will not gain access to available, cutting-edge medical technologies for many years after they are cleared for marketing in the United States.* And if you add it all up, Mr. Chairman, we are often talking about more than a four-year delay—as we noted earlier. We need to ask ourselves what the value-added benefit of this delay is for patients and medical professionals. We want to stress that we do not see this as intentional on HCFA's part. These systems, as we indicated, were put in place in a piecemeal fashion and were not designed to work together.

Now, we would like to take a few moments to let you know about two issues of significant importance to the industry, which bear on Medicare coverage, coding , and payment policy.

Coverage Issues. A year ago, Mr. Chairman, HCFA instituted a new process for making national coverage determinations on medical technologies. This was a positive change. HCFA opened the process, allowed the public to participate, and provided information on the status of coverage through its web site. HCFA deserves clear credit for these changes.

Yet recently, HCFA announced another policy that may entirely overwhelm whatever progress it made in opening the process. We are referring to the agency's Notice of intent to issue new criteria for making Medicare coverage decisions. In essence, these are the standards that products must meet in order to get covered. We believe that several sections of the Notice of intent conflict with the agency's overall goal of improved patient access.

First, in its Notice, HCFA raises the possibility of denying Medicare coverage of certain technologies on the basis of their cost. HIMA believes that economic factors such as cost properly are considered in the context of payment, not coverage, decisions. In a recent nationwide survey by polling firm Penn, Schoen & Berland, 67% of Americans said they would oppose limiting availability of new technologies on the basis of cost.

Second, we are concerned by the evidentiary burdens presented by the Notice. As new requirements are put in place that define levels of evidence required for device coverage decisions, HCFA must recognize that new devices emanate from a dynamic, incremental innovation process, and that they have very short life cycles. As a result, no one type of information should be required for medical devices. Instead, many different types of evidence must be used to guide clinical use of new technologies, with the evidence tailored to the medical device that is being considered.

Third, we are concerned that the Notice is overly prescriptive and curtails physicians' and patients' ability to decide which medical treatment option is best. Society has entered an era in which patients are playing an increasingly important role in making decisions about their health care. Patients and physicians have a unique role to play in deciding whether, for example, the improved quality of life offered by a new technology outweighs potential risks. Medicare should craft coverage criteria that empower patients and physicians, rather than unnecessarily restricting their ability to decide among different treatment options.

Mr. Chairman, we will be filing comments on this Notice with the agency later this week.

The next issue we would like to discuss relates to a new prospective payment system that HCFA is implementing for hospital outpatient services.

Hospital Outpatient Payment. When HCFA proposed its plan for an outpatient payment system, it based the payment categories and payment levels on data that would have been four years old by the time the system was expected to go into effect. The data would have been seven years old by the time the system would have been updated. This would have left out literally hundreds of critical technologies.

By providing for two-to-three years of market-based pricing before new technologies and devices are folded back into the APC groupings, the Congress assured adequate access to these incredibly important items for Medicare beneficiaries. While the list of eligible devices released by HCFA to date has been inadequate, we are currently working closely with the agency to ensure that the payment system implemented on August 1 recognizes new technologies that were inadequately represented in the data used to design the APC payment categories. We believe this is a critical issue affecting patient access to medical care, and we applaud the Congress for enacting these provisions.

CASE STUDY: THE CORONARY STENT

Mr. Chairman, we would like to present an example of how the shortcomings in all these systems affect one technology, the coronary stent. The coronary stent is a revolutionary device that is inserted into the coronary arteries during angioplasty to reduce narrowing and permit normal blood flow.

As the chart at the end of this statement shows, the device manufacturer first requested a unique code for the device in 1990. But HCFA did not assign the code until 1995—five years later. Once the code was approved, it took the agency another two years—from 1995 to 1997—to gather and analyze data on the product's costs and charges before it set the correct reimbursement level for the stent. Therefore, from the time FDA approved the device in 1994 through the time that HCFA actually arrived at the correct payment level in 1997, hospitals received $3,000 to $5,000 below what it cost them to provide this breakthrough therapy.

Now, consider the impact on patient access. During the time that HCFA reimbursed hospitals at this low level, only between 5-25 percent of eligible Medicare patients received the technology. But once adequate payment was finally approved in 1997, patient access grew. And today, some 70 to 80 percent of eligible patients receive the stent. So, stepping back for just a moment, Mr. Chairman, this case study shows a seven-year process from the time that the code was requested to the time that adequate reimbursement was actually provided.

That can be an eternity in the world of device innovation—where the average life cycle of a technology is often two years or less. And if you are a Medicare patient, you don't want to wait for this kind of technology, while HCFA's policy machinery churns. Please recognize that this occurred at a time when other patients who had private insurance did not have trouble getting access to the stent. In fact, coronary stents became the standard of care long before Medicare got around to paying for them adequately.

ADVAMED RECOMMENDATIONS

We do not come before you, Mr. Chairman, to say that fixing these problems is easy. These problems are, in many cases, a result of years of complex rules layered upon complex rules; problems that are as much matters of perspective as they are problems of structure and operations.

Nevertheless, there are a series of practical steps that can be taken to address them. These steps should be helpful in guiding your thinking as you contemplate HCFA's operations and management.

First, we believe that HCFA must place top priority on streamlining its coverage, coding, and payment systems to dramatically shorten the overall four and one-half year process.

Second, we believe that HCFA should institute reforms that encourage the rapid assimilation of new technologies into the Medicare beneficiary plan.

Third, we believe that HCFA should update all of its payment systems more frequently—at least annually—to reflect changes in medical technology.

What we are advocating, Mr. Chairman, is more timely beneficiary access to new medical technologies.

CONCLUSION

In conclusion, Mr. Chairman, we want you to know that we appreciate the important role this Committee played in improving FDA regulation of medical technology. Unfortunately, the promise of FDA reform—that is, prompt availability of technologies for patients' has not been fulfilled because too many Medicare policies are not working. We look forward to working with this and other committees in addressing these problems.

Mr. Chairman, we also have a request. We want to make the Committee aware of, and ask that it support, a recently introduced piece of legislation that would begin addressing some of the issues we have raised in this statement.

The legislation, H.R. 4935, is entitled "The Medicare Patient Access to Technology Act of 2000," and it was introduced by Representatives Jim Ramstad and Karen Thurman. Several Members of this Subcommittee have co-sponsored this legislation. This bill digs into the nuts-and-bolts of HCFA policies that affect innovation—from coding timetables, to the type of data that HCFA insists upon, to how frequently payment systems should be updated—and it offers practical solutions.

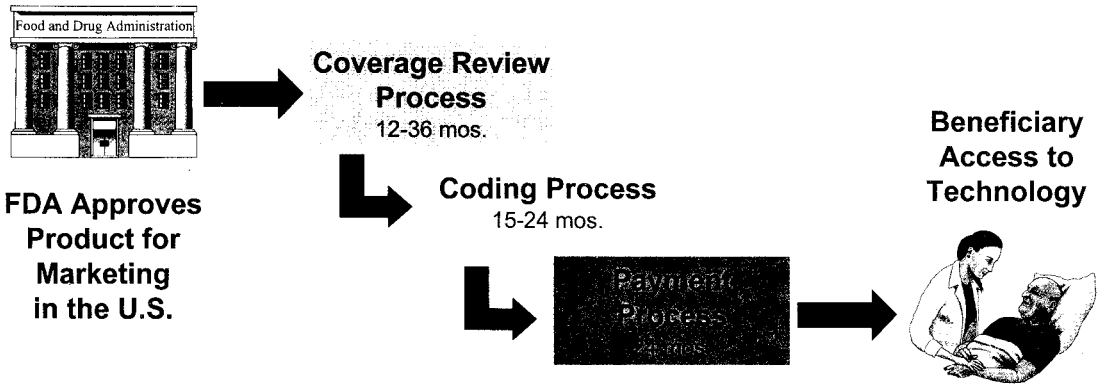
It also takes a holistic view of HCFA's performance regarding medical technologies in that it would require the agency to report annually on how long it took during the preceding year to make coverage, coding, and payment policy determinations on a technology-specific basis. Such a report would create useful benchmarks against which HCFA's performance can be more easily measured, understood, and reformed.

We view this legislation as a down payment in the larger effort to modernize HCFA, and we ask your support for it, and we urge you to consider including it in any appropriate Medicare bill you may take up this year.

We at AdvaMed are currently studying the structure of the agency and plan to have additional views on how HCFA can be more responsive to beneficiary needs for timely access to new and innovative medical technologies.

Thank you for permitting us to offer our views on this important matter.

CURRENT HCFA APPROVAL PROCESS CAN TAKE 4 1/2 YEARS

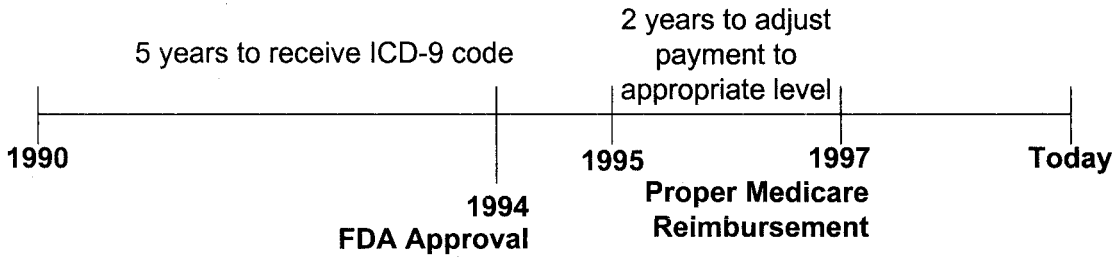


Coronary Stents

A Case Study of Reduced Medicare Patient Access

5% to 25% of eligible patients received the technology 1994-1997

70% to 80% of eligible patients now receive the technology



Mr. BILIRAKIS. Mr. Mangano, please proceed.

STATEMENT OF MICHAEL F. MANGANO

Mr. MANGANO. Thank you, Mr. Chairman. I appreciate the opportunity to be with you here today to give you an update on the efforts and results of our continuing fight against fraud, waste and abuse in the Medicare Program, as well as to address the question of this hearing of Medicare's complexity as it affects the patient's access to quality care.

At the outset, I want to make it clear that we believe the overwhelming majority of health care providers in this country are honest and provide high quality care. When we talk about fraud, we are talking about those who would intentionally set out to steal from the Medicare Program, act in reckless disregard of its rules or deliberate ignorance of the truth.

Thanks to your leadership, Mr. Chairman, and this committee, several years ago the Congress passed an Insurance Portability and Accountability Act which required the Secretary, working through the Inspector General, as well as the Attorney General, to work together in a coordinated program to address these problems in the Medicare Program.

The committee also provided the necessary resources to enable us to mount a successful effort. We are grateful to the Congress for that legislation. I can tell you today that it is reaping a lot of results, very positive ones.

In the last 3 years we have produced savings of over $31 billion. That is comprised of $226 million in audit disallowances, over $2 billion in investigative receivables, and over $28 billion in terms of changes in law and regulations recommended by our office.

Even more important, we helped HCFA reduce its error rate from a level of $23 billion 4 years ago to $13.5 billion. That is an annual savings of just under $10 billion. Every dollar of that we can say was achieved without a single beneficiary losing an eligible service or a health care provider being denied a legitimate compensation, $13.5 billion in improper claims is still too much.

According to the Congressional Budget Office and Medicare trustees, our efforts have contributed to the lowest inflation rate in Medicare's entire history and an extension of the solvency of the trust fund after 2025, which is about a 26-year extension just based on the work in the last 3 years.

But this is not a time to let our guard down. My testimony presents numerous examples of fraud in the system that we still need to pay attention to.

I next want to turn to the question of whether complexity in the Medicare Program is threatening access to quality care. We are well aware of the growing complexity of Medicare due to its numerous amendments and regulations to put those amendments into effect.

The methods of reimbursement changing in the Medicare system, the cost base, the charge base, the prospective pay and fee schedules, as well as the structure of the entire health care delivery system today emphasizing managed care and vertical and horizontal integration.

Periods of transition like we are going through right now are always taxing and uncomfortable for those involved in that system change. Are Medicare rules too complicated to understand? On the basis of our work, sometimes they are.

When we find that to be the case, we recommend to HCFA that they do simplify them. I also want to say that on the basis of our annual review of the Medicare error rates, that 92 percent of all the claims that we reviewed, the national statistical sample, are free of errors, suggesting that most health care providers are getting it right.

HCFA has placed some additional burdens on health care providers, some of which we think are legitimate. Those providers in that category are subject to some of the pre- and post-payment edits that are designed around services that we have been finding are particularly abusive. In fact we have recommended some of those edits.

But very few health care claims in total actually go through this more intensive scrutiny. One of the things that we have tried to emphasize in the last 3 years is a operative working relationship with the health care community in developing voluntary guidance to help them avoid some of the innocent billing mistakes, but also to help them discover more abusive practices that may be occurring in the organizations that they are not aware of.

All of these are paying handsome dividends like the drop in the error rate, lowest inflation rate in years and the 26-year extension of the trust fund.

I might add that these have also had a positive effect on beneficiaries in that they are paying lower co-payments and are actually receiving the service they are supposed to be receiving because of this additional scrutiny. We think that is possible because health care providers are generally doing a much better job complying with the rules, and we are doing a better job in catching the errors where they exist.

Finally, I do not believe this complexity has resulted in a threat to patient access to quality care on the basis of the reviews that we have done in the areas that we have looked.

Recent reviews that we have undertaken with hospital discharge planners and nursing home administrators show that beneficiaries are getting placed in nursing homes and home health without serious problems. We will continue to watch these closely, though, to see if changes occur over the years.

Mr. Chairman, this completes my testimony and I would be happy to answer any questions.

[The prepared statement of Michael F. Magano follows:]

PREPARED STATEMENT OF MICHAEL F. MANGANO, PRINCIPAL DEPUTY INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning Mr. Chairman. My name is Michael F. Mangano. I am Principal Deputy Inspector General for the Department of Health and Human Services (HHS). It is my pleasure to be here today to give you an update on our efforts and accomplishments in our continuing fight against waste, fraud and abuse in the Medicare program as well as address the question of the complexity of the Health Care Financing Administration (HCFA) as it affects potential access to quality of care.

In summary, we are fully engaged and making good progress. We continue to believe that most health care providers do their best to provide high quality care and

are honest in their dealings with Medicare. When we talk about fraud, we are not talking about providers who make innocent billing errors, but rather those who intentionally set out to defraud the Medicare program or abuse Medicare beneficiaries. The importance of our ongoing work is not only to protect the taxpayers and ensure quality healthcare for Medicare beneficiaries, but to also make the Medicare environment one in which honest providers can operate on a level-playing field and do not find themselves in unfair competition with criminals.

At the same time, we must be concerned about all errors, even those which are totally innocent. The complexity of the program places an obligation on health care providers, beneficiaries, fiscal intermediaries, carriers, and HCFA to take reasonable care to comply with its rules. Thus, our audits and studies are also intended to identify vulnerabilities to administrative errors and to the related dollar losses which can be quite significant. In addition, our reviews show that Medicare complexity has not been an impediment to patient access to care nor has it imposed unreasonable burdens on most health care providers.

As a result of an unparalleled coordinated and cooperative response to the problem of health care waste, fraud and abuse by the Congress and the Administration, particularly through the landmark pieces of legislation—the Health Insurance Portability and Accountability Act of 1996, we have been able to expose and measure the problem more completely and accurately than ever before. It is bigger, more sophisticated, and more formidable than many may have imagined. But we are more fully armed, have better tools, and are better organized than in the past. As a result, we have recently had some notable successes and are confident of favorable outcomes on several fronts. And we feel fully supported by allies in every branch and unit of government as well as by the healthcare community and senior advocacy groups.

However, we must temper our optimism and remain vigilant. Due to the complexity of the Medicare program and the tremendous number of dollars flowing through the program, there will always be those who will continue to seek loopholes and look for ways to siphon those dollars earmarked for maintaining and improving the health of the elderly and disabled in this country.

BACKGROUND

The Office of Inspector General (OIG) was created in 1976 and is statutorily charged with protecting the integrity of our Department's programs, as well as promoting their economy, efficiency and effectiveness. The OIG meets this statutory mandate through a comprehensive program of audits, program evaluations, and investigations designed to improve the management of the department and to protect its programs and beneficiaries from fraud, waste and abuse. Our role is to detect and prevent waste, fraud and abuse, and to ensure that beneficiaries receive high quality, necessary services, at appropriate payment levels.

The Health Care Financing Administration (HCFA) is the largest single purchaser of health care in the world. With expenditures of approximately $310 billion, assets of $181 billion, and liabilities of $40 billion, HCFA is also the largest component of the Department. Medicare and Medicaid outlays represent 34.2 cents of every dollar of health care spent in the United States in 1998. The Medicare program is inherently at high risk for payment errors due to its size as well as its complex reimbursement rules, and decentralized operations (39 million beneficiaries and 860 million claims processed annually).

RECENT ACCOMPLISHMENTS

Many specific, positive changes have been made to shore up the over $200 billion Medicare program and its payment methods. Thanks to increased resources provided through recent legislation, our Department, the Department of Justice (DoJ), and related agencies at the State and Federal levels now have better authority and capacity to fight fraud and to reduce waste in all federally-funded health care programs. We have also strengthened our efforts to prevent fraud, waste, and abuse from occurring in the first place.

HIPAA Accomplishments—Increased Recoveries, Exclusions, Convictions, and Settlements

The Fraud and Abuse Control Program, a key part of the Health Insurance Portability and Accountability Act of 1996, enabled us to boost our efforts in identifying and preventing waste, fraud and abuse in Medicare. This program provides much needed resources, stronger enforcement tools, and a management structure to coordinate the efforts of numerous fraud fighting units of Federal, State, and local governments.

The program is under the joint direction of the Attorney General and the Secretary of Health and Human Services, working through the Inspector General. It mandates a comprehensive program of investigations, audits, and evaluations of health care delivery; authorizes new criminal, civil, and administrative remedies; requires guidance to the health care industry about potentially fraudulent health care practices; and establishes a national data bank to receive and report final adverse actions imposed against health care providers. The Act also provides an innovative mechanism to fund these new anti-fraud efforts, thereby assuring that needed resources are always available for the effort.

We are grateful to the Congress in passing this landmark legislation and we are pleased to report that we are already reaping substantial benefits of the additional resources and authorities. In the past three under HIPAA (FY 1997 through FY 1999), we have reported overall savings of $31.0 billion. This is comprised of $226 million in audit disallowances, $2.1 billion in investigative receivables, and $28.7 billion in savings from implemented legislative or regulatory recommendations and actions to put funds to better use. The savings that result from our recommendations that are implemented into law or regulation, and independently scored by the Congressional Budget Office or HCFA, represent taxpayer or Medicare Trust Fund dollars that will not be spent.

During this same period, we excluded more than 8,697 abusive or fraudulent individuals and entities from doing business with Medicare, Medicaid, and other Federal and State health care programs. Additional accomplishments include 1,085 convictions of individuals or entities that engaged in crimes against departmental programs. We increased convictions by nearly 20 percent in 1997, another 16 percent in 1998, and by almost 54 percent in 1999.

Medicare Fee-For-Service Payment Error Rate

The OIG recently issued its fourth report on the Medicare fee-for service payment error rate. Based on a statistically valid sample, improper payments totaled an estimated $13.5 billion, or about 8.0 percent of the $169.5 billion in FY 1999 processed fee-for-service payments. Improper payments include those for: unsupported services, medically unnecessary services, errors due to incorrect coding, and noncovered services. Over the four years we have conducted this review, the improper payment rate declined by 42 percent, from a midpoint of $23.2 billion (14 percent) in 1996, to $13.5 billion (8.0 percent) in FY 1999—a drop of $9.7 billion. This represents a cut in Medicare costs without a single beneficiary being denied a needed service or a health care provider being denied legitimate compensation.

Many Medicare watchers attribute at least part of this downward trend to the increased oversight and enforcement efforts of our office, HCFA, DoJ and the FBI that were made possible by the steady funding stream created by HIPAA. According to the Medicare Trustees and the Congressional Budget Office, these waste, fraud and abuse efforts contributed to Medicare's lowest inflation rate in history and the extension of the viability of the Trust Fund until 2025—a 26 year extension brought about over the last three years.

Waste, Fraud and Abuse Prevention

The OIG has continued to expand activities designed not just to uncover existing waste, fraud and abuse, but to prevent it. A cornerstone of our prevention efforts has been the development of compliance program guidance to encourage and enlist the private health care industry in the fight against waste, fraud and abuse. The guidance is developed in cooperation with the provider community and identifies steps that health care providers may voluntarily take to improve their compliance with Medicare and Medicaid rules. We have published eight compliance guidance documents covering hospitals, clinical laboratories, home health agencies, third-party billing companies, durable medical equipment, hospices, Medicare + Choice organizations, and nursing facilities. We have recently invited comments on our draft guidance related to individual physicians and small group practices.

OIG has also increased its activities with respect to monitoring settlement agreements with integrity provisions and corporate integrity agreements that have been entered into by health care providers as part of a global settlement of OIG investigations and audits. The current caseload of approximately 440 is expected in increase to over 475 by the end of 2000. Our efforts to focus on preventing health care fraud also includes guidance to the industry on the propriety of health care transactions. OIG has published two significant final regulations creating 10 new safe harbors to the Federal anti-kickback statute. Finally, the OIG continues to promote beneficiary involvement in identifying fraudulent activities. This includes operating our HHS hotline which currently receives approximately 48,000 calls per month.

CONTINUING VULNERABILITIES

We in the Office of Inspector General are heartened by the support we have received from the Congress, Administration, as well as by the healthcare community and senior advocates in our fight against fraud, waste, and abuse in the Medicare program. At the same time, our new authorities and resources have enabled us to see more clearly just how pervasive and overwhelming these problems are. While our recent error estimates in the fee-for-service part of Medicare shows a general decline, it is still too high; all money improperly paid is wasteful. Additionally, these audits do not detect well known forms of fraud such as kickbacks or deliberate forgery of bills or supporting documents. Further, whatever the audits reveal or fail to reveal, we know from our investigations and from complaints that we receive that waste, fraud and abuse are still pervasive in the health care sector.

All of this is to say that we cannot take much time out of our fight against fraud, waste, and abuse. We are still watching all areas of Medicare through our audits, inspections, and investigations. And we are continuing to encourage and receive support from industry and beneficiary groups in our efforts. At this time, however, I would like to single out some areas where we continue to have special concerns and give some examples of the results of several significant audits and investigations.

Partial Hospitalization and Community Mental Health Centers

In collaboration with the Department, we examined the growth of Medicare expenditures to community mental health centers for partial hospitalization services (highly intensive psychiatric services) and found that Medicare was paying for services to beneficiaries who had no history of mental illness and for therapy sessions that consisted of only recreational and diversionary activities, such as watching television, dancing, and playing games. Our review in five States, which accounted for 77 percent of partial hospitalization payments to mental health centers nationally during 1996, disclosed that Medicare paid $229 million for unallowable and highly questionable services. Ninety-one percent of the services reviewed did not meet Medicare reimbursement requirements. Reviews of 20 individual centers by both OIG and HCFA disclosed similar problems. In response to our recommendations, HCFA instituted extensive corrective actions, including terminating egregious centers, conducting intensified medical reviews, and collecting overpayments.

Hospital Outpatient Psychiatric Services

The OIG conducted a 10-State review of outpatient psychiatric services, which accounted for 77 percent of the value of partial hospitalization program and other outpatient psychiatric claims at acute care hospitals nationally. Our final report estimates that in the ten States reviewed, about $225 million of $381.9 million (almost 60 percent) in 1997 outpatient psychiatric claims made by hospitals did not meet Medicare's reimbursement requirements. These unallowable services included: services not reasonable and necessary for the patient's condition; services not authorized and/or supervised by a physician; services not adequately documented or not documented at all; and, services rendered by unlicenced personnel. Reviews at individual acute care hospitals disclosed problems with unsupported and medically unnecessary services and unallowable costs included on the hospital cost reports.

Home Health

Looking behind the explosive growth in Medicare expenditures for home health care since 1990, OIG, using claims data from 1995 through part of 1996, found that 40 percent of the payments were improper. We also determined that many home health agencies shared characteristics that could undermine the Department's ability to recover overpayments or levy sanctions. Our recommendations to strengthen the Medicare certification process and to otherwise protect the trust fund were adopted in the Balanced Budget Act of 1997. Conducted at the Department's request, our follow-up work, which examined 1998 claims data, noted that the payment error rate had fallen to 19 percent. Below is an egregious example of misappropriation of Medicare funds and potential abuse of Medicare patients by a home health agency which we audited as part of our Operation Restore Trust effort.

St. John's Home Health Agency

In our audit of St. John's Home Health Agency, the highest paid home health agency in South Florida, we found that St. John's billed Medicare for non-rendered or upcoded home health services and that nurses and home health aids permitted subcontracting groups to use their name and/or create fraudulent documents to support nonrendered services. We also found that some nursing visits were provided by unlicenced persons. Further, we found that subcontractors paid kickbacks to St.

John's employees in order to do business with them. Twenty-six people were indicted in December 1999 for racketeering, conspiring to racketeer, conspiring to launder money and conspiring to submit false claims to the Medicare program. Subsequent to plea or trial, there were 24 guilty verdicts (one individual became a fugitive and one was acquitted); all 24 guilty verdicts are in the process of being excluded.

Medicare Contractors

The Medicare program is administered by the Health Care Financing Administration (HCFA) with the help of 64 contractors that handle claims processing and administration. The contractors are responsible for paying health care providers for the services provided under Medicare fee-for-service, providing a full accounting of funds, and conducting activities designed to safeguard the program and its funds. There are two types of contractors—fiscal intermediaries and carriers. Intermediaries process claims filed under Part A of the Medicare program from institutions, such as hospitals and skilled nursing facilities; carriers process claims under Part B of the program from other health care providers such as physicians and medical equipment suppliers.

Of all the problems we have observed, perhaps the most troubling has to do with contractors' own integrity—misusing government funds and actively trying to conceal their actions, altering documents and falsifying statements that specific work was performed. In some cases, contractors prepared bogus documents to falsely demonstrate superior performance for which Medicare rewarded them with bonuses and additional contracts. In other examples, contractors adjusted their claims processing so that system edits designed to prevent inappropriate payments were turned off, resulting in misspent Medicare Trust Fund dollars. We have also encountered problems associated with financial management and accounting procedures and longstanding weaknesses in internal controls, including deficiencies related to the receivable amounts reported in HCFA's financial statements and electronic data processing.

In addition, there have been numerous allegations that contractors have falsified statements that specific work was performed, and altered, removed, concealed, and destroyed documents to improve their ratings on Medicare performance evaluations. Wrongdoing has been identified and we have entered into civil settlements with 13 Medicare contractors since 1993, with total settlements exceeding $350 million. In addition, two contractors have entered into guilty pleas for obstruction of a federal audit.

Fresenius Medical Care Holdings, Inc.

The government recently reached a record-breaking Medicare fraud settlement with Fresenius Medical Care Holdings, Inc. (FMCH), the Nation's largest provider of kidney dialysis products and services. As a result of a joint investigation by OIG and multiple law enforcement agencies and an OIG audit, FMCH agreed to a global resolution under which three subsidiaries pled guilty, and the company agreed to pay $486 million to resolve the criminal and civil aspects of the case. As part of the civil settlement agreement for credit balances, the company paid directly to HCFA $11 million for overpayments which were previously reported to the fiscal intermediaries but never recouped. The alleged criminal misconduct involved illegal kickback activity, submission of false claims for dialysis-related nutrition therapy services, improper billing for laboratory services and false reporting of credit balances. This misconduct was engaged in by National Medical Care, a nationwide dialysis company, and various of its subsidiaries prior to a 1996 merger with FMCH. As part of the settlement, the company also entered into the most comprehensive corporate integrity agreement ever imposed by OIG.

COMPLEXITY OF MEDICARE AND IMPACT ON PATIENT ACCESS

Increasing Complexity

Since the inception of Medicare, numerous legislative changes have been made and amendments added to the Social Security Act which have led to substantial changes to the Medicare program. With each addition, HCFA is required to develop new regulations as well as update its contractor and provider rules and guidelines. For example, the Balanced Budget Act of 1997 contained 335 provisions related to Medicare programs, including mandates for new prospective payment systems in several programs, which required the development of a substantial number of new regulations.

Much of the complexity in the Medicare program is not inherent in the program itself, but rather it parallels the ever increasing complexity of our health care system. For example, the development of various forms of managed care and new kinds

of vertical and horizontal integration have led to the need for Medicare rules and regulations to evolve along with them.

Additionally, the way Medicare pays for health care has changed through time, from primarily cost/charge based payment systems to new fee-schedule and prospective based arrangements. For example, hospital inpatient, physician, then lab and durable medical equipment services were the first areas of the program to switch to prospective payment or fee schedule based payment systems. More recently, skilled nursing facility, home health, and hospital outpatient services have moved or are moving to prospective payment systems as well. This transitioning from one payment system to another inevitably involves an intensive and somewhat uncomfortable learning period. In the long run, it is hoped that these new payment systems will simplify and reduce the administrative burdens of providers.

Provider Burden

Is the Medicare payment system too difficult to understand? In some cases our audits and evaluations do indicate that some rules are unnecessarily complex and burdensome. In such cases, we make recommendations for simplification. However, our recent error rate review would indicate that providers are doing a very good job of negotiating their way through Medicare payment systems—we found that 92 percent of all claims submitted by health care providers are free of error. In the substantial majority of cases, legitimate providers are billing for legitimate services.

We do recognize that HCFA has placed some additional burdens on the health care providers. Many of these, however, we think are legitimate and some have been instituted from IG recommendations based on past abuses we have found in the system. For example, to sustain its progress in reducing payment errors, we have recommended that HCFA:

- Enhance prepayment and postpayment controls by updating computer systems and related software technology to better detect improper Medicare payments;
- Expand provider training to further emphasize the need to maintain medical records containing sufficient documentation, as well as to use proper procedure codes when billing Medicare for services provided;
- Direct its Peer Review Organizations to identify high-risk areas and reinstate selected surveillance initiatives, such as hospital readmission reviews and diagnosis related group (DRG) coding reviews; and,
- Continue to refine Medicare regulations and guidelines to provide the best possible assurance that medical procedures and services are correctly coded and sufficiently documented.

It should be noted, however, that very few health care claims are subjected to this more intense review. For example, while some 660,000 physicians receive Medicare payments each year, HCFA only reviews about 5 percent of physician claims. Additionally, we continue to work with industry sectors to develop voluntary guidance to help them avoid innocent billing errors as well as discover and/or prevent more abusive practices within their organizations. This will help to ensure that they can avoid any unnecessary scrutiny.

Prior to HIPAA, the efforts of HCFA, the OIG, and DoJ to identify and prevent waste, fraud, and abuse in health care was far less than adequate. With the new infusion of resources, we have been able to get serious. Some of the impact has been greater scrutiny of certain types of providers and more care by providers in general to bill properly. For example, there has been more scrutiny by HCFA of home health and intensive psychiatric services as a result of our identifying serious abuse by some providers. As a result of these efforts we have realized:

- A 42 percent drop in the Medicare fee-for-service error rate;
- An extension of the solvency of the Medicare Trust fund by 26 years; and,
- The lowest inflation rate in Medicare history.

These results have had a positive effect on beneficiaries as well. The lower inflation rate, and our greater scrutiny of claims, means that beneficiaries pay lower copayments and receive the services they really need. These have been possible because health care providers are doing a better job of complying with Medicare rules and we are doing a better job in catching the errors and more serious attempts to defraud the Medicare program.

Patient Access to Quality Care

We do not believe that the complexity of the Medicare program has resulted in a threat to patient access to quality of care in the areas we have examined. For example, we studied the impact of the new nursing home prospective payment system on access to care. We found that Medicare patients are able to access care in skilled nursing facilities, particularly therapy patients. In fact, we found that it is easier to place Medicare therapy patients in nursing homes after the new payment system

went into effect than before. Further, in a recent inspection looking at how the interim payment system for home health agencies is affecting Medicare beneficiaries' access to home health care for patients discharged from hospitals, we found that 85 percent of discharge planners report that Medicare patients are able to obtain home health care when they need it and three quarters said that they need to only contact one home health care agency on average to arrange for that care. We will continue to monitor access to these services as well as other areas in the health care system.

In general, we see that the failure of enforcing provisions, rather than the increased complexity of rules and regulations, has led to improper and poor quality of care. For example, dollars spent on psychiatric patients to watch television, could and should have been put to better use in providing appropriate and high quality mental health care for these beneficiaries.

CONCLUSION

As I stated at the beginning of my testimony, I believe a concentrated effort by a large number of people has resulted in tangible progress in combating fraud, waste, and abuse in recent years. But as I have also discussed with you today, the problems that remain are serious, complicated, and have profound consequences. I am particularly concerned about the deliberate fraud which we cannot always measure but that we know continues. We must never let down our guard, and we must continue to dedicate the resources and make the concerted effort to reduce these problems.

We in the Office of Inspector General will be actively overseeing how the new resources and safeguards provided in the HIPAA are used to determine their effectiveness in preventing and combating criminal activities. For true criminals, the only effective safeguards are tough-minded program measures to prevent fraud and a strong law enforcement presence with equally strong penalties applied to defrauders.

It must be recognized that some of these efforts have led to an increased burden on some providers. Put into context however, it also must be recognized that this is a small price to pay to extend the viability of the Medicare Trust Fund and ensure health care for our elderly and disabled for another 26 years. This concludes my testimony.

I greatly appreciate the opportunity you have given me today to focus attention on the continuing problems and vulnerabilities that confront the Medicare Program and to share with you our progress as the result of some of our recent efforts and initiatives. I would be happy to answer any questions.

Mr. BILIRAKIS. Thank you. I would like to ask, is anyone from HCFA still here or have they all left? They have all left. As Dr. Norwood commented, they certainly should be here to hear this testimony, but we did not request that.

Mr. COBURN. They have to get back and answer all those letters. Mr. Chairman, for the record to note, nobody is here from HCFA hearing this testimony.

Mr. BILIRAKIS. That is right.

HCFA REPRESENTATIVE. I am here as a note-taker.

Mr. BILIRAKIS. Then HCFA is represented. Okay, you will share then some of this testimony with them.

Dr. Coble?

STATEMENT OF YANK COBLE

Mr. COBLE. Thank you, Mr. Chairman and members of the subcommittee. My name is Yank Coble. I am Secretary-Treasurer of the American Medical Association Board of Trustees. I practice endocrinology in Jacksonville, Florida.

We appreciate very much the opportunity to testify on the complexity of Medicare regulations and how they adversely affect patient care and physician's practices throughout the country.

Physicians are now subject to over 100,000 pages of rules and regulations as you have heard several times. They by far exceed the IRS code. It has gotten to the point where Medicare regulations

are flooding physicians' offices. There is not a month that goes by that HCFA or the OIG does not issue a complex new Medicare regulations which impacts physicians and their patients.

As a result, physicians have to devote many more hours each week to comply with these ever changing Medicare rules and regulations. These are hours that physicians cannot spend on patient care.

Indeed, many physicians are now so frustrated with the volume of regulations and how they are being vilified by HCFA that they are less and less willing to see new Medicare patients. In rural communities we are experiencing the effects of this dissatisfaction with the program by seeing entire practices pull out of the Medicare Program.

Even in Denver, Colorado, there is now a shortage of physicians who will see Medicare patients. Even in my own case, because of the regulations governing Medicare diabetes patients, I have gradually over recent years stopped seeing those patients in my practice.

Congress recognized that HCFA had to address those regulatory hassles when it created the Practicing Physicians Advisory Council, PPAC, nearly a decade ago. Unfortunately, HCFA has never effectively used this valuable resource, despite repeated promises to make PPAC more effective.

Instead, 3 years ago, HCFA created an internal task force, the Physician Regulatory Initiative Team, PRIT, to examine the regulatory burden on physicians. PRIT has yet to issue a final report, eliminate a single regulation or simplify Medicare rules and regulations.

To make matters worse, physicians have been unable to obtain clear and consistent information on billing, coding and documentation questions from their carriers because carriers also generally refuse to answer physician's queries in writing, physicians are unable to obtain a file copy if a question later arises.

The communication process does not improve a great deal during the post-payment audit process. The carrier simply mails a letter to the physician requesting records and later informs them of a projected over-payment.

In addition to written requests, carriers should telephone physicians to request records and should maintain a dialog with physicians prior to the onset of a formal audit and settlement process.

These communications should specifically cite possible improper billing, appending post-payment audit, the outcome of the audit and the physician's appeal rights.

I have several broader examples that I would like to share with the subcommittee explaining how HCFA's over zealousness and refusal to abide by statutory mandates has either compromised patient care or has limited patient access to physicians.

The first example concerns hospice rules. The Wall Street Journal recently reported that the government contracted with a private company to notify hospice patients who exceeded their 6-month life expectancy that they were no longer entitled to hospice benefits.

Hospice benefits should not be cutoff if a patient happens to live longer than 6 months. The government contractor is incorrectly in-

terpreting the hospice statute which, of course, is resulting in patient harm. HCFA should remedy this problem immediately.

The second example concerns physician post-payment audits. Medicare carriers can audit physician records many years after claims have been paid by conducting post-payment audits.

Currently, unless a physician agrees to open her office to additional audits on top of the original audit, the physician has to waive all of her rights and agree to repay a projected overpayment amount. These projected amounts can bankrupt physician's practices.

We believe that HCFA should be required to institute due process protections for physicians undergoing post-payment audits which would allow an overpayment determination be appealed to an administrative law judge.

Finally, the sustainable growth rate, SGR, which Congress addressed in 1999 with the Balanced Budget Refinement Act, is another area where HCFA is not adhering to its statutory mandate.

As the committee knows, the SGR sets a target rate of spending growth based on four factors, one of which applies to legislative and regulatory changes affecting physician expenditures. I emphasize "regulatory." However, HCFA has not factored in the new regulatory burdens for purposes of calculating changes to the SGR.

We urge Congress to ensure that HCFA meets its statutory obligations by considering both statutory and regulatory changes before formulating the SGR.

The AMA has numerous concerns regarding recent HCFA and carrier activities. We have included these additional issues in our written testimony, which I would also be happy to discuss here at a later time.

Thank you for the opportunity to share our concerns of how HCFA regulations negatively impact patient care and their access to physicians in the Medicare Program.

We urge Congress to undertake the HCFA reform effort as it did with the IRS several years ago, removing some of these regulatory burdens to allow physicians to redirect efforts toward providing patient care.

We thank you.

[The prepared statement of Yank Coble follows:]

PREPARED STATEMENT OF YANK D. COBLE, BOARD OF DIRECTORS, AMERICAN MEDICAL ASSOCIATION

Mr. Chairman and members of the Subcommittee, my name is Dr. Yank D. Coble, and I am a practicing endocrinologist from Jacksonville, Florida, and the Secretary-Treasurer of the American Medical Association (AMA) Board of Trustees. On behalf of the 300,000 physician and medical student members of the AMA, I would like to thank you for holding this extremely important hearing to examine the activities of the Health Care Financing Administration (HCFA) and the negative impact their policies have on patient care and physicians treating Medicare patients. The AMA serves as an umbrella organization for over 90 medical specialty societies who also have numerous and extensive concerns regarding different HCFA regulations, which are broader than those mentioned in our statement. We appreciate this opportunity to testify, and we urge the Subcommittee to continue these hearings to explore the widespread concern across the entire physician community with HCFA policies and those of its carriers.

America's physicians have reached a point where the volume of Medicare regulations, combined with the fear that they may be unnecessarily and unfairly audited, have prompted them to question whether they should continue to accept new Medicare patients. America's patients and their physicians are harmed by many of these

unneeded regulations, which cause physicians to spend far too much time on paperwork and less time providing patient care. This seriously diminishes patient access to care. For example, in the well-populated city of Denver, Colorado, there is no longer a sufficient number of physicians for the patient population willing to participate in the Medicare program. In rural areas, such as Idaho, the impact of fewer physicians involved in the Medicare program can be especially devastating.

We hope this hearing will demonstrate that HCFA must recognize the burdens placed on physicians and providers by its regulatory agenda. The agency has issued volumes of regulations and policies that are overly burdensome, confusing, conflicting and selectively enforced. The AMA has vigorously contested many of the HCFA policies that negatively impact physicians and the patients we serve, but to date, HCFA has not been able to make serious progress in streamlining its regulations.

In fact, we believe HCFA has squandered its many opportunities to streamline the process through the use of the Practicing Physician Advisory Council (PPAC), a federal advisory committee, which Congress established almost a decade ago with the AMA's support. PPAC is comprised of fifteen private practice physicians and providers who meet quarterly. It is supposed to advise the Secretary of the Department of Health and Human Services and the HCFA Administrator on prospective policy issues impacting the physician community and the Medicare/Medicaid programs as a result of contemplated or current federal rulemaking. The Congress enacted this legislation because of physicians' concerns about the "hassle factor" involved in dealing with the Medicare program. Unfortunately, the Administration has never effectively used this potentially valuable resource despite repeated promises to make it more effective.

Three years ago, HCFA engaged in a well-publicized campaign to respond to the growing concern about regulatory burdens on physicians. Unfortunately, HCFA again failed to seriously employ the expertise of the practicing physicians on PPAC. Instead, the agency formed an internal work group known as the Physician Regulatory Initiative Team (PRIT). PRIT has never issued a final report, eliminated a single regulation, or simplified the morass of rules, regulations, and memorandums that govern the Medicare program. The AMA certainly supports the worthwhile intent of both PPAC and the PRIT. After three years, however, there is little evidence to indicate that HCFA will successfully reduce the burden or hassles that confront physicians and their patients.

For purposes of this hearing, we will focus on several specific, yet illustrative, examples of regulations run amok, as well as additional concerns related to the lack of a communication process between HCFA, its carriers and physicians.

Regulations . . . and More Regulations

Health care is a highly regulated profession, and HCFA is overzealous in its regulatory scope and enforcement activities. Physicians are subject to over 100,000 pages of Medicare regulations and policies, including the preambles and accompanying text to the regulations, which attempt to explain the intent of the often convoluted and ambiguous regulations. These materials, however, often raise more questions than they answer. Further, in addition to new and existing regulations, physicians must be familiar with the volumes of ever-changing bulletins and carrier materials sent to their offices.

In fact, HCFA, the Office of the Inspector General (OIG), and other federal agencies continuously issue new regulations that apply to physicians, providers, and their patients. To truly understand these regulations and policies and their impact on their practices, physicians would have to hire scores of attorneys and consultants. In his testimony to the House Budget Committee Health Task Force last week, Dr. Robert Berenson, Director of the Center for Health Plans and Providers at HCFA, tried to justify the vast number of HCFA regulations during the past several years by stating that the agency has had to respond to 335 statutory changes as a result of provisions in the Balanced Budget Act of 1997 (BBA). Many of these statutory changes were translated into new and extremely complex regulations for physicians and other providers. These 335 statutory changes and their regulations are in addition to the other regulations issued during this time by other agencies and entities that regulate physicians. We have attached a chart to our statement depicting the vast regulatory structure that govern physicians and their practices.

We offer the following examples to illustrate the extent to which several of the many HCFA regulations and policies place burdens on physician practices and are increasingly out-of-touch with patients' health care needs:

Hospice Rules—The *Wall Street Journal* reported on June 5, 2000, that the government contracted with a private company to notify hospice patients that their benefits expired because the patients had exceeded their six-month life expectancy,

which entitled them to hospice benefits. The article recounted heart-wrenching stories of many patients being forced into nursing homes as a result of the contractor terminating their hospice benefits. In accordance with HCFA's hospice policy, if a physician believes that a patient's life expectancy will not exceed six months, then the patient can qualify for hospice benefits. If a patient outlives this six-month limit, these patients' hospice benefits should not be withdrawn. This is a further instance of HCFA regulations and government contractor actions that contradict congressional intent and directly cause patient harm. (Article attached.)

Post-Payment Audits—Physicians should enjoy the same due process rights as taxpayers undergoing IRS audits who can appeal IRS fines, penalties, and findings. To the contrary, once a carrier conducts a post-payment audit of a physician's practice, the carrier determines the amount of projected Medicare overpayments through an extrapolation process. Since the amount is determined through extrapolation, it can easily rise to tens of thousands of dollars. Once carriers arrive at this projected overpayment amount, carriers give physicians three options: (1) repay the extrapolated amount and waive their appeal rights; (2) repay the extrapolated amount and submit additional information while waiving their appeal rights; or (3) open up their practice to a statistically valid random sampling (SVRS) of claims during the same time period. HCFA's carrier manual options prevent physicians from retaining their due process rights *unless* they agree to open up their practices to a larger SVRS audit. This is patently unfair, and many physicians feel compelled to agree to settlements to avoid a burdensome, expensive, and protracted SVRS audit. Targeting physicians in this manner will result in physicians restricting their Medicare practices, thereby decreasing patient access to these physicians.

HCFA should be required to alter its carrier manual instructions to ensure that physicians undergoing post-payment audits are not forced to waive their due process rights. Passage of H.R. 3300, introduced by Representative Shelley Berkeley, would remedy the current post-payment audit process and would address many of the broader Medicare education issues for physicians that are addressed later in this statement.

Overpayment Audits—The AMA understands that HCFA has instructed its carriers to begin auditing physicians who submit too large of an overpayment remittance to HCFA. According to *Part B News,* HCFA has also told carriers to launch an audit if the carrier suspects "a pattern of inappropriate payment." HCFA should *encourage* this voluntary refund of overpayments, rather than target honest physicians who are attempting to return overpayments to their carriers. As discussed with respect to post-payment audits, targeting physicians in this manner will result in physicians restricting their Medicare practices, thereby decreasing patient access to these physicians. **We therefore recommend that HCFA be prohibited from targeting physicians for audits based solely on the fact that they have voluntarily refunded overpayments.**

Self-Referral—Physicians considering any type of an ownership interest in any facility or thinking of providing additional services within their own practice have to hire attorneys to advise them on how to attempt to stay within the bounds of these regulations. Physicians must also get legal advice before they receive anything of value from any entity to which they refer patients.

The intent of the self-referral statutes was to prevent overutilization of services due to physician ownership in facilities—not to limit patient access to care and micromanage physician practices and contracting arrangements. This regulation has transgressed well beyond the intent of the statute. HCFA plans to release the final regulations this year, and we anticipate they will create an extremely high anxiety level among physicians regarding their contracting arrangements and the internal workings of their practices. **The AMA supports H.R. 2651, the "Physician Self Referral Amendments of 1999," which would streamline the self-referral laws for physicians, leading to increased access for patients, particularly in rural areas.**

Impact of Regulations on the Sustainable Growth Rate (SGR)

The SGR system is a further example of the need for Congress to exercise diligent and ongoing oversight of HCFA. The SGR sets a target rate of spending growth based on four factors: changes in payments for physician services before legislative adjustments (essentially inflation); changes in Medicare fee-for-service enrollment; changes in real per capita gross domestic product (GDP); *and an allowance for legislative and regulatory factors affecting physician expenditures.*

We appeared before this Subcommittee last year to discuss erroneous projections by HCFA during the first two years of the SGR (1998 and 1999) and HCFA's decision to renege on its pledge to correct these errors, despite the agency's decision

having no statutory basis. These errors shortchanged physician payments by more than $3 billion.

In response, Congress enacted provisions under the Balanced Budget Refinement Act of 1999 (BBRA) to ensure that HCFA meets its statutory obligation to correct its projection errors and appropriately pay physicians for Medicare items and services furnished to patients.

The AMA appreciates the Subcommittee's responsiveness and strong oversight of HCFA on this matter. While HCFA has begun to comply with the SGR statutory provisions under the BBRA, the agency has nevertheless determined that it will ignore another statutory mandate established under the original SGR formula enacted under the BBA. That is, for purposes of establishing the SGR, HCFA is not permitting the proper allowance for changes in legislative *and regulatory* factors affecting physician expenditures despite being required by statute to do so.

In HCFA's April 10, 2000, *Federal Register* notice of the SGR for calendar year 2000, the agency explained that only "legislative changes contained in the BBA and the BBRA will have an impact on expenditures for physicians' services under the SGR in CY 2000." Although HCFA appears to have factored the impact of these statutory changes into the CY 2000 SGR, it did not discuss factoring into the SGR any impact resulting from *regulatory* changes. As we discussed earlier, HCFA has been promulgating hundreds of regulations in response to the BBA and other laws, many of which impact physician expenditures.

HCFA's disregard of this statutory mandate is further exemplified by the fact that the agency regularly fails to develop appropriate and accurate regulatory impact analyses with respect to the various regulations promulgated by the agency. Although the law requires HCFA to establish such analyses, the agency's estimates are light-years away from representing the actual impact of the regulation on practicing physicians and often do not even take into account any impact on physicians.

For example, HCFA requires beneficiaries with diabetes to have their prescriptions for diabetes test strips renewed by their physician every 6 months. The rules that were developed by Medicare's durable medical equipment carriers governing these test strips have imposed an enormous burden on physicians, yet this burden has never been included in any regulatory impact analysis under any HCFA rule. This burden, in turn, adversely impacts patient access to care—the more physicians are forced to focus on burdensome regulatory requirements, the less time can be spent on patient care.

HCFA recently testified before Congress that the AMA is overstating the size of the regulatory burden that Medicare imposes on physicians. HCFA implied that most of the rules it issues do not have any effect on physicians and that the number of pages of final regulations affecting physicians is quite small. In fact, however, nearly every rule published by HCFA imposes new burdens on physicians. These rules and policies include not only the final regulations established by the agency, but what has become a constant stream of Program Memorandums, Operational Policy Letters, and carrier bulletins.

The result of HCFA's behavior is that physicians are forced to invest an ever-increasing proportion of their resources on the heavy paperwork burden. The resources could be better utilized on investment in new medical technologies and expansion of patient care services. The quality of our nation's health care system depends on physicians being able to spend their time on patient care, not paperwork.

Accordingly, we urge the Subcommittee to ensure that HCFA meets the statutory obligations mandated by Congress and prevent HCFA from engaging in abusive tactics that exceed its discretionary authority. Specifically, HCFA should be directed to conduct more accurate regulatory impact analyses and to account for the regulatory burden on all those affected by a regulation, physicians providers and patients. Further, we urge Congress to direct HCFA to account accurately for the cost of Medicare rules, policies, and regulations in the calculation of each year's SGR.

Ineffective Communication with Carriers and Physicians

Increasingly, HCFA appears to be making decisions in a vacuum. Once it was common practice for the agency to consult with medical organizations prior to issuing rules expected to have a significant impact on physician practices. At that time, practical considerations as well as policy implications could be hashed out in advance of publication and many problems were altogether avoided.

For a variety of reasons, including HCFA staff reductions, reorganizations, and the burdens imposed by the BBA, this sort of consultation is a rare occurrence today. Rather, communications in the current environment are increasingly one-sided with edicts issued with little attempt to determine whether the order is either reasonable or necessary. Items that ought to be covered in a proposed rule instead

are released and implemented through directives to the contractors who administer the Medicare program. Alternatively, they are placed in a final rule, effectively sidestepping the requirement that major changes in Medicare policy go through a public comment period. **We urge Congress to ensure that HCFA adheres to the strictures of the Administrative Procedures Act in its issuance of new rules and regulations.**

Seclusion and Restraints

One of the most egregious examples of HCFA's propensity for making arbitrary and unilateral decisions occurred last summer with the release of an interim final rule on one section of a plan to modify Medicare's conditions of participation. Included in the rule was a new provision that would require a face-to-face evaluation by a physician or licensed independent practitioner within one hour of the application of seclusion or restraints to patients with behavioral health problems.

This rule, which went into effect just 30 days after it was issued, constitutes a major change in clinical practice that was never tested in the general population. Yet it was put into place without any prior consultation with hospitals and physicians, and without clarifying guidelines, which were not issued until ten months after the rule went into effect. This rule has the potential to significantly increase hospital costs, disrupt care of other patients and further jeopardize the continued existence of some small rural hospitals.

The Joint Commission on Accreditation of Healthcare Organizations, using a much more deliberative, patient-focused and scientifically-based process, came up with a less stringent rule, but HCFA has refused to modify the provision and, nearly a year later, still has not issued a final rule acknowledging and responding to the thousands of negative comments it received on the one-hour requirement.

Critical Care Codes

Another example of HCFA failing to consider advice from practicing physicians, and thereby adversely impacting patient care, is the development of policy concerning critical care codes. Due to inconsistent interpretations by HCFA carriers, affected medical specialties asked the CPT (Common Procedural Terminology) Panel of the AMA which develops procedure codes, to redefine what constitutes critical care services. Even though HCFA participated as a member of this procedure coding committee, no strong objections were heard from HCFA about the resulting definition. In the final fee schedule regulation notice, HCFA indicated its disagreement with the CPT Panel, and reduced the payment levels for these codes by 10 percent based on the assumption that more services would be billed as critical care.

The effect of that decision is that Medicare pays substantially lower payments to physicians who treat the most critically ill patients. The consequences of this ill-conceived policy are obvious—its creates perverse incentives and thus physicians will be forced to spend less time with critically ill patients, who, ironically, are in most need of a physician's time and care.

After repeated expressions of alarm from the medical profession about the impact of the lower values on these essential services, HCFA agreed to ask the CPT Panel to again revisit the definition of critical care services. **Both sides have now agreed on a mutually acceptable definition of critical care, but HCFA has not yet restored the correct payment levels for these codes.**

Communication with Individual Physicians

Physicians must have the ability to contact HCFA or its carriers and receive a reliable and consistent response to questions concerning claims for patient services. Physicians are often a beneficiary's link to Medicare with regard to the translation of Medicare coverage decisions. Improved communication between carriers and physicians will ultimately result in better informed patients.

HCFA and its carriers, however, do not adequately communicate with and conduct educational initiatives for physicians. For example, in a February 1999 Report entitled, "Ordering Medicare Equipment and Supplies—Physicians' Perspectives," the OIG confirmed that "75 percent of physicians reported they have never received any educational materials from their Medicare carrier concerning the equipment and supply ordering process."

Physicians document patient visits and submit hundreds of claims to the program during every month. If these claims submitted to carriers are not done correctly, physicians can be subjected to investigations, audits, and penalties.

Use of a general website alone to educate physicians and inform them of changes to coding, documentation and coverage policies is not sufficient. Physicians have great difficulty in securing specific answers from their carriers regarding these im-

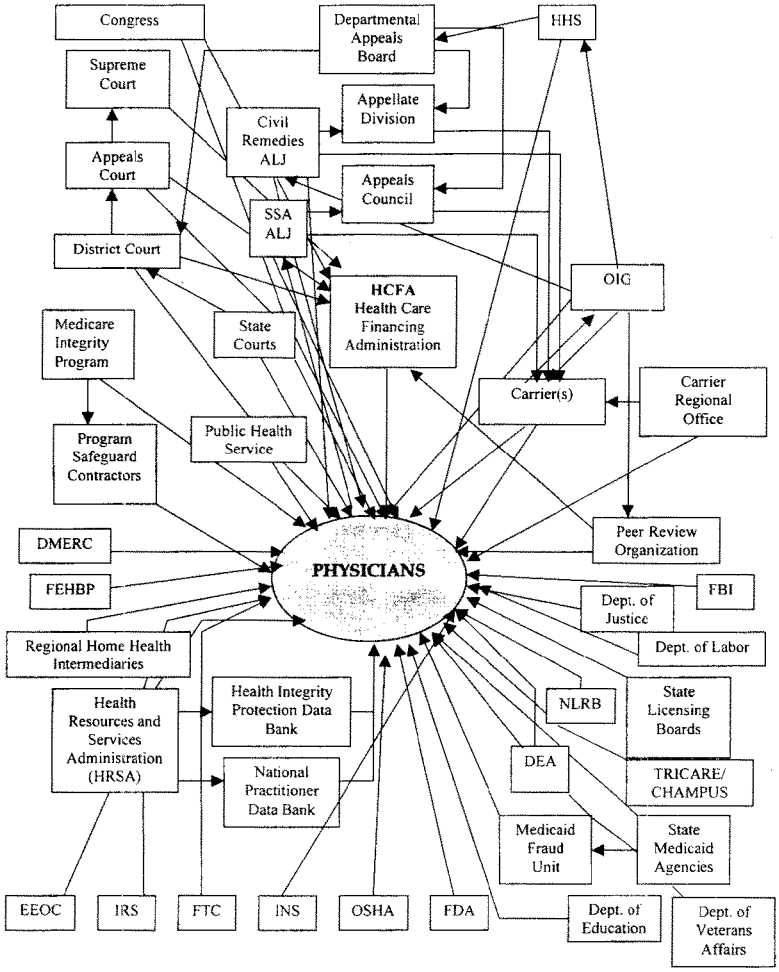
portant coding, documentation, and coverage policy questions. Carrier staff frequently provide inconsistent answers to critical questions. In addition, most carriers refuse to answer physicians' queries in writing, so the physician can maintain a copy of the correspondence for his or her records. After years of asking HCFA to reinstitute toll-free lines for physicians, the AMA was pleased when HCFA agreed this spring to reopen these lines. While these toll-free lines are not a cure-all, the AMA hopes that these carrier lines will be adequately funded and will begin to address physicians' questions regarding the Medicare program.

The processes that HCFA uses during post-payment audits are also antiquated and ineffective. For instance, when carriers audit physician practices, physicians receive a letter, which carries no special designation or marking, requesting records via regular mail. Physicians' offices receive lab reports, payments from government, private, and individual payors in addition to other correspondence related to practice management in their daily mail deliveries. **The AMA recommends that carriers orally communicate with physicians concerning a records request and maintain a dialogue throughout the audit and settlement processes concerning compliance activities with respect to any alleged physician billing errors. Specifically, HCFA should require its carriers to contact physicians orally and in writing to inform them of: possible improper billing, a pending post-payment audit, the outcome of the audit, and the physician's appeal rights.**

As the foregoing discussion demonstrates, physicians have serious concerns with HCFA's management of the Medicare fee-for-service program, in which 85 percent of the Medicare population is enrolled. These deficiencies demand Congress' serious and immediate attention. While our testimony has attempted to cover several major areas where HCFA oversight is desperately needed, we also have concerns with numerous other policies, which we would pleased to discuss with the Subcommittee at a later date or at a later hearing. We would be happy to discuss any of these issues in more detail, and look forward to working on these issues more extensively with the Subcommittee in the months to come.

Government Entities Looking Over Physicians' Shoulders

Prepared by AMA Division of Legislative Counsel, 5/15/00



Mr. BILIRAKIS. Thank you very much, Dr. Coble.
Ms. Gottlich?

STATEMENT OF VICKI GOTTLICH

Ms. GOTTLICH. I am Vicki Gottlich. I am with the Center for Medicare Advocacy. I am also representing the National Academy of Elder Law Attorneys.

Center advocates and NAELA attorneys have direct experience in counseling and representing older people, people with disabilities and their families. The center responds to over 1500 calls about Medicare and other health issues each quarter on a toll-free hotline.

As of last Friday, we have 13,342 open cases involving access to Medicare benefits. We also work to assure access to employer-sponsored health insurance and have been counsel and provided technical assistance in litigation to secure health care rights for participants in private health plans.

Our experience has given us the opportunity to compare the difficulties of Medicare beneficiaries in obtaining necessary health care with the difficulties of plan participants under private health insurance.

Despite our past and ongoing differences with HCFA, and these include several of the issues mentioned today such as preauthorization, such as coverage determinations, we have determined that HCFA does a much better job in administering Medicare and in protecting beneficiary rights than private insurance companies do in protecting the rights of private plan participants.

The added protection comes from regulations and guidance that implement Medicare from the accountability of HCFA as a government agency and from increased participation of beneficiaries and their advocates in HCFA processes.

Regulations are issued pursuant to directions from Congress in order to protect Medicare beneficiary rights. Though there are a lot of Medicare+Choice regulations, these really implement a very detailed, complex program.

The best example we have is the rules promulgated to implement the Nursing Home Reform Law. They were imposing standards that were really best practices that very few nursing homes were using.

But after they were implemented, the reduced use of physical and chemical restraints improved quality for residents and other savings resulted in annual estimated savings to the Medicare Program of $2 billion in hospital costs in 1992 dollars.

Regulations set standards. When a client comes to us who is a Medicare beneficiary and says "I have been denied nursing home care because I don't meet the definition of skilled care," we know where to find it in the regulations and in the manuals.

When the same client comes to us or a different client and has the same issue in private health insurance, there are no regulations. There are no standards and there are no easy ways to get those regulations and the standards from the health plans.

We end up with clients who have been denied care even though they meet the Medicare regulations for the definition of skilled care.

When HMOs terminate their coverage, they provide notices that are readable, they provide people explanation of their rights upon the termination of their HMO. This is all because of regulations and HCFA's involvement in trying to protect beneficiaries.

Private health insurance plans that terminate their coverage do so without any notice to beneficiaries at all. The four notices that HCFA is working to improve actually are being improved. We have had lots of complaints about them over the years. I think some of the efforts are due to some of our litigation.

But the form notices that we see from private health insurance many times do not even comply with the standards of ERISA. I have never seen one that gave a good explanation of why coverage had been terminated and what rights there are.

Medicare beneficiaries are protected by the accountability of HCFA as a Federal Government agency. As an agency it must promulgate regulations. It must have open meetings. It must appoint advisory committees that comply with FACA.

Most importantly, it is subject to hearings such as this one where, when people have problems with HCFA, we can rake them over the coals or interrogate them. That is not true of private health insurance plans. We have no opportunity as beneficiary representatives to work with private health insurance plans to deal with the systemic problems that we see on behalf of our clients.

HCFA has also made a great effort in the past few years to increase beneficiary access, so we can have the opportunity to talk to HCFA about our problems, to discuss with HCFA some of the changes that it is planning to make.

We are very concerned that some of the proposals under consideration to change the way the Medicare Program is managed would increase rather than decrease beneficiary vulnerability.

Privatization of management of the Medicare Program removes the protections provided by government management of Federal programs.

We are concerned that private entities don't operate as efficiently as Medicare, raising the concern that more Medicare dollars would be spent on administrative costs if programs are managed by private entities.

We also are very fearful about the proposal to bifurcate the administration of Medicare between two entities. We are fearful this will cause confusion for Medicare beneficiaries.

We envision a bureaucratic nightmare of coordinating information about one program between two agencies that will exasperate duplicative administrative, unnecessary paperwork and cost delays.

What we would like to see would be some efficiencies that have already been discussed in terms of streamlining time lines. We would like to see additional resources given to HCFA so they could improve the work that they are doing.

We thank you for the opportunity to participate today.

[The prepared statement of Vicki Gottlich follows:]

PREPARED STATEMENT OF VICKI GOTTLICH, ATTORNEY, CENTER FOR MEDICARE ADVOCACY, INC.

Introduction

Good morning. I am Vicki Gottlich, a staff attorney with the Healthcare Rights Project of the Center for Medicare Advocacy, Inc., (the Center) and chair of the Sub-

committee on Managed Care, Public Policy Committee of the National Academy of Elder Law Attorneys (NAELA). I appreciate the opportunity to address the Subcommittee on Health and Environment of the Commerce Committee on behalf of these two organizations. We, like you, are concerned with the important issue of HCFA's role in Medicare management.

Center advocates and NAELA attorneys have direct experience in counseling and representing older people, people with disabilities, and their families. The Center for Medicare Advocacy responds to over 1,500 calls about Medicare and other health issues each quarter on a toll free telephone line in Connecticut. As of June 23, we have 13,342 open cases involving access to Medicare benefits. Members of the Center's legal staff have been leaders in advancing Medicare coverage and due process rights and access to health care through class action litigation and administrative advocacy.

Most recently, in *Grijalva v. Shalala,* a nationwide class action, the Center was successful in obtaining a court order which established due process rights for Medicare managed care enrollees throughout the United States. In *Healey v. Shalala,* we represent a nationwide class and have successfully challenged the manner in which Medicare beneficiaries are denied home health benefits and services. Finally, Center staff and NAELA members also work to assure access to employer-sponsored health insurance, and have been counsel and provided technical assistance in litigation to secure health care rights for participants in private health plans.

Our experience has given us the opportunity to compare the difficulties of Medicare beneficiaries in obtaining necessary health care with the difficulties of plan participants under private health plans. Despite our past and on-going differences with HCFA over the administration of the Medicare program, we believe strongly that HCFA does a better job in administering Medicare and in protecting beneficiary rights than private insurance companies do in protecting the rights of their participants. The added protection to beneficiaries comes from the national regulations and guidance that define program policy and standards in implementing the Medicare program, from the accountability of HCFA as a government agency, and from the increased participation of beneficiaries and their advocates in HCFA processes.

Regulations Are Issued Pursuant to Directions from Congress in Order to Protect Medicare Beneficiary Rights

Some health care providers contend that the voluminous Medicare regulations make it impossible to provide services under the program and impede access to care. We disagree. Medicare regulations are issued by HCFA to implement the changes in the laws passed by Congress, to protect the rights of Medicare beneficiaries to receive medically necessary services, and to assure accountability of providers and of HCFA. For example:

- The Balanced Budget Act of 1997 included a specific statutory section, 42 U.S.C. § 1395w-26, that directed HCFA (a) to establish standards for financial solvency of Medicare+Choice plans, and (b) to establish other standards to carry out the new Medicare Part C, the Medicare+Choice program. Other statutory sections relating to Part C directed HCFA to address specific substantive issues, for example, standards for exercising choice and electing a Medicare+Choice plan, guidelines for post-stabilization care, and time periods for appeals of adverse determinations, and included details about what should be included in the regulations. Thus, the nearly 100 pages of interim final regulations[1] added to the Code of Federal Regulations to implement the Medicare+Choice program were done so at the explicit direction of Congress to help with the administration of this new and very complex program.
- Federal Medicare and Medicaid rules promulgated by HCFA to implement the Nursing Home Reform Law of 1987 have led to reduced use of physical and chemical restraints in many skilled nursing facilities nationwide, allowing facilities to provide better care for residents at lower cost. They also led to a 30% increase in the use of hearing aids; an increase in use of toileting programs for incontinent residents; a 28% decrease in the proportion of residents with little or no activity; and a 26% reduction in hospitalizations of residents (resulting in an annual estimated savings to the Medicare program of $2 billion in hospital costs in 1992 dollars)[2].

---

[1] Final regulations to implement the Medicare+Choice program have been posted on the HCFA web page and are expected to be published in the Federal Register this week.

[2] Dr. Catherine Hawes, *Assuring Nursing Home Quality: The History and Impact of Federal Standards in OBRA-1987* (Commonwealth Fund, December 1996).

Regulations, HCFA Manuals and Other Guidance, and Form Letters Provide Standards That Help Beneficiaries Know Whether They Have Received the Benefits to Which They Are Entitled.

Medicare regulations and other guidance developed by HCFA help assure that beneficiaries receive the services they need. Private insurance provides no similar protection for plan participants. For example:

- We consistently are asked to assist Medicare beneficiaries and private health plan participants who have been denied home health or nursing home benefits on the grounds that the care they need is not skilled care. While 42 C.F.R. Sections 409.32 and 409.33 (approximately three pages) define the criteria for and give examples of skilled care for the Medicare program, no similar standards exist under the Employee Retirement Income Security Act (ERISA), which governs private employer and union-sponsored insurance, or under the majority of private health plans I have examined over the years. The lack of standards leaves clients in private plans unsure about their coverage and results in frequent benefit denials. In a case from Indianapolis last year, the claims workers for a large insurance company covering a large employer stated in depositions that they were given different and inconsistent information about what was skilled care, and ended up rejecting virtually every claim. Had the client in that case been covered under Medicare, his care needs would have met the regulatory definition of skilled care.
- Medicare regulations and HCFA guidance require HMOs which terminate their contracts with HCFA to give their enrollees advance notice of the termination and to explain their rights upon termination. The HMOs use model notices developed by HCFA to help assure readability and understanding by the beneficiaries. When private insurance companies terminate their contracts with employers, they are not required to provide advance notice to plan participants, or to inform them of the other health plans in which they may enroll. Employers are not required to maintain one consistent, standard plan, such as traditional Medicare, to which their employees may return.
- Form notices developed by HCFA to explain what services have been covered, what services have been denied, why they have been denied, and what a beneficiary can do about a denied service provide accurate information and consistency.[3] There is no consistency in the form notices provided by private insurers; each insurer has its own forms. Many do not meet the notice requirements of ERISA.
- Beneficiaries are more vulnerable when HCFA does not mandate forms. Last year, I served as a consumer representative to an informal work group designed to assist HCFA in the development of a standardized summary of benefits (SB) form for Medicare+Choice HMOs. Most of the SB forms developed by the private insurers offering Medicare+Choice plans that I reviewed as a part of the process were not beneficiary friendly. The form SB developed through HCFA contains accurate descriptions of Medicare benefits and was focus group-tested to assure comprehension and readability. As a result, the SB will be a better education piece for beneficiaries and a better marketing tool for Medicare+Choice plans.

Medicare Beneficiaries Are Protected by the Accountability of HCFA as a Federal Government Agency.

Because HCFA is a federal government agency, it must meet the requirements of all agencies to make public its meetings, to publish its proposed standards and regulations, and to appoint advisory committees that comply with the Federal Advisory Committee Act (FACA), Pub. L. 92-463, 5 U.S.C. App. 2. The administration of its budget is subject to oversight, as are the workings of the agency as a whole. This very hearing is evidence of the high level of accountability to which HCFA is held. As a result, beneficiaries have greater assurance that the administration of the Medicare program is being monitored closely and that they will have an opportunity to participate in decisions that affect their program. For example:

- HCFA is revising the process for deciding the particular services and technologies to be covered and paid for by Medicare. We have been very visible in our complaints about the coverage determination process, through litigation,[4] through

[3] Several of the revisions to forms and notices have come as a direct result of litigation conducted by Center and NAELA attorneys. See, for example, *Grijalva v. Shalala, supra,* (managed care appeals notices); *Healey v. Shalala, supra,* (home health termination notices), and *Sarrassat v. Sullivan,* (N.D. Cal. 1989) (nursing home discharge notices).

[4] See, e.g., *Jameson v. Bowen,* C.A. No. CV-F-83-547-REC (E.D. Cal.1987), and *Richey v. Shalala,* CV (W.D. Tex. Feb. 1, 2000)

testimony before HCFA's Medicare Coverage Advisory Committee (MCAC), and through testimony at Congressional and other briefings. We intend to file comments vigorously objecting to HCFA's proposed criteria for making determinations, published in the Federal Register in May.[5] We can only engage in such advocacy on behalf of Medicare beneficiaries because of the openness of the government process. There is no similar mechanism for participation in or contesting the process for deciding what services and technologies will be covered under private health insurance plans, even those that are collectively bargained.

- When HCFA decides to change its regulations, it allows beneficiaries and others to comment on the effect of the changes on them and their ability to receive medically necessary care. For example, as part of interim final regulations published in 1998 to implement a prospective payment system (PPS) for Medicare skilled nursing facility benefits, HCFA deleted from the regulations sections which give examples of certain nursing services that are considered skilled care.[6] Because the sections and examples also apply to skilled care in the context of home health benefits, the deletion generated confusion about the scope of the regulations. The Center filed comments on the regulations and wrote to HCFA Administrator Nancy-Ann Min Deparle for clarification of the extend of their applicability. Ms. Deparle responded that others had also expressed confusion, and that HCFA did not intend the deletion of regulatory sections to mean that they "... no longer regard these services as appropriate examples of skilled care."[7] The final PPS regulations, issued in July 1999,[8] responded to the comments and reinserted the deleted sections. This process of first proposing changes to standards and soliciting comments is not available for private insurance.

Increased Access to HCFA and its Processes Assures Greater Beneficiary Participation and Protection.

In recent years, HCFA has come to understand the importance of including beneficiaries and beneficiary concerns in its administration of the Medicare program. In HCFA parlance, they have determined that beneficiaries are their "customer." Though we still question HCFA's understanding of the importance of beneficiaries to the Medicare program, we have seen improvements, especially in regards to information and education.

- In response to complaints by beneficiary representatives, HCFA several years ago changed the quarterly beneficiary meetings to monthly meetings. These meetings have turned from "show and tell" programs whose agendas were dictated by HCFA to meetings in which beneficiaries have dialogues with HCFA staff responsible for administering Medicare, Medicaid and the state children's health initiative program.
- Because of their increased emphasis on beneficiaries, their reaching out to beneficiary representatives, and their responsibility as a public entity administering a public program, HCFA's efforts are highly improved and more effective for beneficiaries than the efforts we have seen from private insurance. HCFA initially developed its managed care marketing guidelines with in-put only from plan representatives. When beneficiary and consumer organizations were asked to review the final product HCFA and the plan representatives had developed, they found that the guidelines contained information that was inaccurate and confusing and that the guidelines did not explain fully the rights of beneficiaries enrolled in managed care.
- HCFA has established two separate entities to assist with Medicare+Choice education and information. The National Medicare Education Partnership (NMEP) coordinates with organizations representing a variety of interests—beneficiaries, plans, employers, unions, government—to assure that beneficiaries receive accurate and adequate explanations of their Medicare benefits and the choices available under the Medicare+Choice program. The Center for Medicare Advocacy serves as a member of the NMEP Coordinating Committee. The ten-member Citizens Advisory Panel on Medicare Education (APME) is a FACA authorized committee designed to assist HCFA with its statutorily mandated Medicare+Choice education efforts.

---

[5] 65 Fed. Reg. 31124 (May 16, 2000).
[6] 42 C.F.R. § 409.33(a)(1)-(3).
[7] Letter from HCFA Administrator Deparle, April 28, 1999, www.medicareadvocacy.org.
[8] 64 Fed. Reg. 41670, (July 30, 1999).

HCFA Has Done a Gone Job Satisfying The Beneficiary Education Obligations Imposed by the BBA.

Congress in the Balanced Budget Act imposed a very heavy burden upon HCFA to provide beneficiary education. The BBA requires HCFA to establish and maintain an Internet site to provide information, to conduct annual information fairs, to maintain a toll-free hotline, and to send out annual mailings to each Medicare beneficiary that not only describe the Medicare program but that include the Medicare+Choice options available in the different communities. The solution to problems observed in the education component is not to take the responsibility for education away from HCFA, but to assure that HCFA has adequate funding and staff to do a good job.

- HCFA has done a remarkable job, given the financial constraints imposed by Congress, the lack of staff, and the complexity of the Medicare+Choice program. Thanks to comments by NMEP members and others, the *Medicare and You Handbook* improves each year. The information about plan choices on the Internet is reasonably accurate, and HCFA continuously works to make the site more useable. I have personally called the 1-800-MEDICARE hotline number to test its accuracy, and I have been given correct information even when I asked complex, difficult questions. On the other hand, clients who have sought information from their health plans directly have been given incomplete or incorrect information, including being told that they have no right to appeal an adverse determination.
- The problems with HCFA's education program stem from the growing complexity of the Medicare+Choice program and not the failure of HCFA's initiatives. The Center for Medicare Advocacy requires three days to train volunteers for CHOICES, the Connecticut state health insurance counseling program, about Medicare and Medicare+Choice. When HCFA tried to describe the new Private Fee For Service plan to the NMEP coordinating committee, it quickly became apparent that even NMEP members who are knowledgeable about Medicare needed more time to understand the complexities of this option.

Proposals to Change the Way the Medicare Program is Managed Would Increase, Rather Than Decrease, Beneficiary Vulnerability.

Current proposals to change the way the Medicare program is managed would harm beneficiaries dramatically by reducing their access to the administrators of the program, removing many of the protections available to them, and causing confusion in management.

- Proposals to biforcate the administration of Medicare between two entities, regardless of whether the second entity is a federal government agency, will cause confusion for Medicare beneficiaries. Beneficiaries will not know to which of the entities to turn with their questions, particularly when questions fall within the jurisdiction of both entities. Our clients who are dually eligible for Medicare and Medicaid would have to seek out information from both entities, since HCFA will retain jurisdiction over Medicaid, and possibly from their state Medicaid agency as well. Clients with functional disabilities and mental impairments will be harder to reach and serve. The bureaucratic nightmare of coordinating information about one program between two agencies will exacerbate problems of duplicative administration, unnecessary paperwork, and delay. The costs of program administration will increase unnecessarily.
- Privatization of the management of the Medicare program removes the protections provided by government management of federal programs. Private entities may not have to meet the same requirements concerning open meetings, appointed advisory committees that are representative of all interested parties, promulgation of standards through a prescribed regulatory process that allows for public comment.
- Private entities do not operate as efficiently as Medicare, raising the concern that more Medicare dollars would be spent on administrative costs if the program were managed by a private entity. Data from 1997, the most recent year posted on HCFA's web site, indicate that administrative expenses were 1.2% of benefit payments for Part A and 2.0% of benefit payments for Part B.[9] The Office of Inspector General (OIG) recently found, on the other hand, that from 1996 through 1999 the average amount allocated by a managed care organization for administration ranged from 3% to 32%. The OIG recommended that HCFA set

[9] HCFA, Office of Strategic Planning: Data from the Division of Medicare and Medicaid Cost Estimates; www.hcfa.gov/stats/hstats98/blustat4.htm.

a ceiling for administrative rates of 15%.[10] Since proposals calling for private administration of Medicare would allow the private entity to pay its chief administrators more than civil service rates, there is no indication that current cost of administering private entities would decrease. Medicare dollars would be spent on administrative costs.

Organizations that represent beneficiary and consumer interests will have difficulty with whatever entity manages the Medicare program. We push constantly to assure that our clients' rights to medically necessary health care are protected in every way. The proposals under consideration—to reduce regulations that set standards and protect beneficiaries, to remove administration of the Medicare program to private entities with fewer obligations to the public interest and the public fisc, and to split the responsibilities for management of Medicare—do nothing to meet the needs of the beneficiaries for whom the program was established. Instead, they would reduce beneficiary rights and their access to care.

Thank you for the opportunity to testify.

Mr. BILIRAKIS. Thank you, Ms. Gottlich.

We understand that the votes might be called about 1:30. That is always a "give or take." Hopefully, we can excuse this panel by the time we have to run to vote. It is up to the members here, I guess.

Dr. Waller, I understand that the Mayo Clinic was approached by HCFA to become a Center of Excellence but declined; is that correct?

Mr. WALLER. That is correct.

Mr. BILIRAKIS. Can you tell us why?

Mr. WALLER. Well, I think that first the regulatory burden and the need to document what we would do in a center of excellence was just far above what we could do. But I think the bottom line to it was that HCFA came to us and said, if you will be a center of excellence, we will name you a center of excellence, if you will take a discount, a discount beyond the price control environment that we have been in since 1984. But we couldn't do that.

The patients who come to Mayo Clinic severity of illness is extraordinarily high when you compare to other practices and the resources needed to take care of patients with severe illness are significant.

So, to be a center of excellence and take a discount for the payments to us was beyond the price controlled environment was not anything that we could do. I guess the bottom line is, though, when we talk to private payers, Mr. Chairman, we can negotiate with them as partners. What can we do to provide quality? What will it cost? How can we work together?

Basically, with all due respect, HCFA said to us, "Here are the rules, take it or leave it." We decided to leave it.

Mr. BILIRAKIS. So, outside of the scope of being designated as a center of excellence, Mayo accepts Medicare patients?

Mr. WALLER. Oh, yes, we do. We take all patients, Medicare patients, Medicaid patients, patients who have no money, patients who have money. We take everybody who comes to our doors.

Mr. BILIRAKIS. Thank you, sir.

Dr. Coble, I have a series of questions here which I am not going to expect you to respond to now because it would take the rest of the time. What are the unnecessary Medicare regulations? What

[10] Office of Inspector General, *Administrative Costs Reflected on the Adjusted Community Rate Proposals Are Inconsistent Among Managed Care Organizations* (A-14-98-00210 January 2000).

rules should be eliminated? What can we do to fix the problems you have described?

In general, do you have a list, does the AMA have a list, of what they consider unnecessary Medicare regulations?

Mr. COBLE. Yes, indeed. I would be happy to provide those to you, sir.

Mr. BILIRAKIS. Do they have a list of the rules that they consider or recommend be eliminated?

Mr. COBLE. Yes. Of course, some of these may be technically rules, some regs, some guidelines and so forth.

Mr. BILIRAKIS. Well, can the AMA furnish that information to this committee?

Mr. COBLE. Yes. We would be delighted to do so.

Mr. BILIRAKIS. All right. Now, that will be in writing.

Now, you referred in your testimony to inquiries made, I guess, regarding coding and the billing by the physicians or providers to HCFA and their responses. Many of those responses, and I believe it was Dr. Coburn who referred to this, that they are quite often not in writing.

What is the significance of their being in writing?

Mr. COBLE. Well, then you can always go back and say this is documentation of what we have been advised and we have complied. But it is very difficult to get that in writing or impossible.

Mr. BILIRAKIS. They won't give it to you in writing, even though you might require it?

Mr. COBURN. Would the chairman yield for just a second?

Mr. BILIRAKIS. Yes.

Mr. COBURN. Personal experience, they will not give you an answer in writing.

Mr. BILIRAKIS. Is that something that the Congress should mandate, Dr. Coble?

Mr. COBLE. We would think that is highly appropriate. It would be very desirable to always be able to identify the person who was talking to you on the phone. Often you cannot get an identification about that individual either.

Mr. BROWN. Is that the carrier or HCFA?

Mr. COBURN. It is the carrier.

Mr. COBLE. It is the carrier.

Mr. COBURN. But the carrier is function under the auspices of HCFA.

Mr. COBLE. They are chosen by HCFA, as I understand it, to function that way.

Mr. BILIRAKIS. If the requirement was that they be in writing, do you think that will slow down the process? Should it slow down the process?

Mr. COBLE. Well, with the availability of faxes and e-mails now, that should be a fairly rapid process.

Mr. BILIRAKIS. So you don't think it should slow down the process?

Mr. COBLE. I certainly would hope not. Our intent is certainly to decrease hassle factors.

Mr. BILIRAKIS. Ms. Gottlich, you refer to 13,000 open cases. I suppose maybe others will get into that. My time is about to expire.

He is a good staffer. He shut the clock off at 4 seconds left. It is a long 4 seconds.

I would hope that you might go into some details regarding that, but I would hope that some of the others will ask that question of you.

I will go ahead and yield to Mr. Brown at this time.

Mr. BROWN. Mr. Mangano, the managed care organizations complain of not enough flexibility, of too much regulation, of not enough reimbursement. I am looking at an IG report that you furnished about administrative costs are not allowable.

Entertainment, gifts, employee morale costs, $69,000 for holiday parties at three MCOs, $190,000 for one sales award meeting in Puerto Rico for one MCO, $249,000 in meeting costs including food, gifts, alcoholic beverages at one MCO. My favorite, $157,000 for a party celebrating a managed care organization's parent company's 150th anniversary. That is taxpayer dollars. Fortunately, you disallowed it.

The MCO solution, when they complain of not enough flexibility, too much regulation, and not enough reimbursement is to minimize HCFA interference and to turn the program over to the private sector. What happens then?

What do you think the result of lessening HCFA oversight on Medicare+Choice plans would be? Would they have flexibility, giving Medicare+Choice plans more flexibility in claiming administrative costs? Talk to me about that.

Mr. MANGANO. Well, I think I remember the report you are talking about. Those costs were not disallowed. In the managed care program HCFA pays a set price for every beneficiary each month. The managed care organization puts a budget together that includes their administrative costs as well as their service delivery costs.

But because it is a Managed Care+Choice plan, the normal rules of Medicare do not apply. In a fee-for-service program, all costs must be reasonable and necessary for the provision of care.

But in managed care, they don't have to apply those rules. So, if a company wants to do those things with their administrative costs, they can do that.

We have recommended to HCFA that they seek legislative change that would apply that rule to the managed care plans as well. That is, that the money should go for patient services rather than some of these more frivolous costs that some of these companies are incurring.

Mr. BROWN. So, under this private part of Medicare that we call Medicare+Choice, the taxpayers paid that $1.5 million that could have gone to patient care.

Mr. MANGANO. That is correct. In our review, looking at the companies nationally, we found that 3 to 32 percent of the money going to managed care plans was spent for administrative costs.

One of the recommendations that we had made was to cap that at 15 percent, which was about the average for the managed care+choice plans. If they did that, that would save about $1 billion that could be used to reduce patient deductibles or to increase services to those beneficiaries.

Mr. BROWN. So it is 3 to 32 percent and you suggest a 15 percent cap. That saves $1 billion plus. Medicare's administrative costs are one to 2 percent; correct?

Mr. MANGANO. That is correct.

Mr. BROWN. So much for the efficiency of the marketplace sometimes.

Mr. MANGANO. What is happening here is that private companies spend money on things that you probably wouldn't want Federal funds to be used for. So, companies do plan to buy sky boxes at sports stadiums, do plan to sponsor golf tournaments and do plan to take yacht trips out on the New York Harbor to look at fireworks.

Mr. BROWN. Not to jump to conclusions, but salaries at the Healthcare Leadership Council members might actually be higher than Mike Hash's salary, too?

Mr. MANGANO. I would suspect that is the case, yes.

Mr. BROWN. Dr. Coble, you mentioned that HCFA's excessive paperwork is taking up valuable time, and I think you are right, time the doctors could be spending with their patients. Some doctors are questioning whether it is worth the effort to see Medicare patients, as I have heard and as you have stated also.

Do you have similar concerns with the private sector? Do you worry the paperwork that the HMOs require is forcing you to compromise on the time you spend with patients and are doctors questioning whether it is worthwhile to practice within an HMO structure also?

Mr. COBLE. Well, there are obviously concerns throughout the system and of course our focus today is on Medicare regulations and that is why I limited my address to that particular issue.

But the changes in regulations that are also somewhat arbitrarily issued, I think, the restraint regulations, the 1-hour rule is an excellent example of this work without any evidence that that is the way in which a patient who in a behavioral health center is placed in restraints for their own safety and the safety of those around them.

We have suddenly the involvement in the medical process that puts burdens and changes in the quality of care in a very diverse country that has very different needs from one part of the country to the other and takes medical decisionmaking away from the patient and the providers and the physicians who are caring for them.

Mr. BROWN. I have admired the American Medical Association's leadership on the Patient's Bill of Rights. Your organization has been one of the major, one of the real fighters for that legislation.

I would guess, if we had more time and if this hearing were focused somewhere else, you would be able to delineate many of those same concerns about private insurance and HMO treatment of physicians that you laid out understanding you were here to talk about HCFA, that you laid out for HCFA today, I assume.

Mr. COBLE. We would certainly attempt to do that, yes. There are opportunities to improve quality of care in every venue imaginable.

Mr. BROWN. Okay. I thank you.

Mr. BILIRAKIS. It looks like we have the bells ringing for a vote.

Dr. Ganske.

Mr. GANSKE. In light of the fact that we will have to leave soon for voting, I am just going to ask one question. One of my concerns with the Republican prescription drug bill is that it really does not define a standard benefit.

I have concerns that it will be difficult for senior citizens to be able to compare one plan to another based on costs and service when there are differences in the underlying benefit. So it is a problem of being able to compare an apple to an apple.

I realize this is a little astray from the hearing, but Dr. Waller, does the Healthcare Leadership Council have any opinion on that particular issue?

Mr. WALLER. Yes, they do. If you look at the Federal Employee Health Benefits Plan, Dr. Ganske, and you look at the plan that Members of Congress have and 59 million employed American, many of them have, there is choice.

One can chose a plan that will provide drug benefits from anywhere from aspirin to chemotherapy. There are other plans that can provide no drug benefits. There are other plans that can provide drug benefits somewhere in the middle.

I think our whole approach to life is providing the Medicare recipients with choice so that they can elect which plan would best suit their needs. So, I think we favor a drug benefit within the framework of comprehensive reform amendment in the nature of as we have spoken in our testimony.

Mr. GANSKE. So you would like to see this issue addressed?

Mr. WALLER. I think we would be concerned about having it be addressed in a piecemeal fashion as an add-on to the current Medicare system. But rather have it incorporated into comprehensive reform according to the principles that we have laid out in our written testimony.

Mr. GANSKE. Dr. Coble, has the AMA taken a position on whether to have a standard package of benefits as versus whatever the insurer wants to offer with "comparable value?"

Mr. COBLE. We haven't taken a position. We have developed some principles that we would like to see considered and not to do something that will create further regulatory hassle and inadequate access and unfair system. We will be happy to provide those principles to the committee.

But we have not looked at the pending bills or the development of bills to have a position on these at this time.

Mr. GANSKE. Mr. Mangano, from the IG's perspective, when you start looking at whether plans are fulfilling their promises, do you have an opinion on whether it would be easier or harder for your office to determine whether in fact a plan is keeping its promises if there are 500 plans out there as versus a requirement that a prescription basically be offered if the physician prescribes it?

Mr. MANGANO. Actually, you know, we haven't taken any position on this issue at all. I know there is wide divergence of views here.

I think that we would be interested in seeing what controls are built into the process to ensure the beneficiaries get what they are supposed to get and that people are not overcharged for, be it the government or the beneficiaries themselves, for the particular drugs that they need to have.

So, we would be looking for any enforcement mechanism that could be put into place to ensure that that happened.

Mr. GANSKE. Do you think it would be useful to look at the President's bill, the administration bill, and the Republican bill in more detail in order to address that issue in the form of some additional hearings?

Mr. MANGANO. For those particular issues, it is certainly something that we would be happy to give our point of view on. But it is really a policy issue, the direction you want to go on.

Mr. GANSKE. I thank you, Mr. Chairman.

Ms. GOTTLICH. Dr. Ganske, I would like to just add to the question you asked. You asked how beneficiaries can chose.

Last year when I was on the subcommittee that worked with plans and HCFA and consumer groups about designing the summary of benefits form, the hardest part to design was the prescription drug section. That is because HMOs do so many different ways of designing the benefit. It was very hard to design language that would help people compare and make a choice.

We know that our beneficiaries chose managed care plans often very much based on the prescription drug benefit that the plan offers.

Because of the confusion, that was the one are of the summary of benefits form where the group could not come to as much consensus as we did in other areas. I think the education and information aspect of having so many different plans is really going to be very difficult for Medicare beneficiaries.

Mr. GANSKE. I thank you.

Mr. BILIRAKIS. Dr. Norwood.

Mr. NORWOOD. Thank you, Mr. Chairman. My observation is, ladies and gentleman, that this hearing is about HCFA, but there have been a lot of shots at the private health care industry which I certainly do agree with.

But I don't want anyone to leave here without understanding the difference. In private health care insurance today there is not public policy. They determine how they operate their plans. Congress gave them that privilege.

Because they are doing bad and HCFA is just doing a little better doesn't mean that HCFA isn't in a great deal of trouble. The difference is HCFA does have public policy. It does have Congressional oversight. It does have people watching what they are doing. And they are still taking 4½ years for an approval process.

So don't leave here thinking because HCFA is only doing better than what we are seeing in the private insurance agency that we don't have a very serious problem going on in this country with health care.

Dr. Coble, I can only speak for the 10th District of Georgia where the Medical College of Georgia is, but the question was asked earlier, are physicians leaving the system?

The answer is: Absolutely. Those in my district over 50, if it isn't Medicare and HCFA driving them crazy, they are trying to get out of it as fast as they can. That is bad for this nation and bad for patients, because you are losing some of your most experienced physicians in America because of what HCFA is doing to them and because of what managed care is doing to them.

Let me say again, I want to make this clear for the record that the people who need to be in this room the most, Mr. Hash and his team, have decided no matter what we hear or learn to date, they don't need to learn it. That is no way we will ever be able to reform HCFA in this country.

Mr. Mangano, let me ask you a question just out of curiosity. You took a great deal of pride, it seems to me, or it was in your voice about the dollars that you saved in waste, fraud and abuse. All of us certainly want that eliminated.

I would appreciate it very much if you would tell me, not now, but in writing, exactly where those dollars come from. I need to understand how many of those dollars have you actually saved, for example, with the subcontractors of HCFA that are terribly inefficient?

How many of those dollars have you saved from physician community and how many of those dollars come from the hospital community?

Explain to me in writing where this money comes from because you implied because of the good work in waste, fraud, and abuse, that our trust fund is now solvent. I have forgotten the year that you said.

Mr. MANGANO. 2025.

Mr. NORWOOD. Because of all this money. I want to understand that better because it is my impression that a great deal of that insolvency came when we transferred home health payments from Part A to Part B.

I'll bet you if we take a close look at that, that is where the biggest savings actually has come. Go ahead and respond.

Mr. MANGANO. The Congressional Budget Office has attributed the solvency extension to three factors: One the lower rate of inflation in the country in general; two, was the Balanced Budget Act provisions; and three was the fraud, waste and abuse efforts.

Mr. NORWOOD. Well, the Balanced Budget Act included the part of home care being transferred from the trust fund to the everyday taxpayer.

Dr. Waller, do you want to comment?

Mr. WALLER. I would just add that we are concerned about the solvency issue. Extending Part A to 2023 is really a misleading statement. It ignores the huge increases in Part B to outpatient services. It ignores the movement, as you have just said, Dr. Norwood, of home health care to Part B.

And it ignores that the way to get to solvency is continued price controls and continued reduction of payments to providers and plans.

The inflation rate also ignores the fact, as Dr. Coburn said earlier, that physicians are constantly over-documenting and undercoding because they are threatened with fraud and abuse.

I think we have to add all those things to the equation when we talk about solvency.

Mr. NORWOOD. I am glad you put that on the record because that should follow behind, well, we are nice and solvent to 2025.

Dr. Coble, would you explain to me, if you can, why it is that HCFA refused to give any consideration to PPAC? Why is it that

they don't use that expertise in their effort to work out the payment system?

Mr. COBLE. I can't, firsthand, answer that. I have talked to the past members of it. They indicate that the agendas are not formed by them, that they have very little input into the agendas. The agendas that are provided to them are often not germane to the real concerns of practicing physicians.

Of course, PPAC is made up by a large percentage, almost the total group are practicing physicians. We understand there has been some attempt to enhance the process in the two most recent meetings, March and June. But I cannot speak specifically to those yet.

Mr. NORWOOD. Well, time is up.

Mr. BILIRAKIS. Time is long up, yes.

Dr. Coburn.

Mr. COBURN. Thank you. I want to share a story. My wife and I were driving down the road 1 day and I just about ran into the back of a truck. She got after me for not paying attention. I had had a couple of wrecks in my 52 years. She said, "you know, I have never had a wreck."

I said, "Yes, but you are forgetting one thing. You have caused hundreds."

To claim that HCFA is efficient and is a great organization is ludicrous. The 2 percent overhead that they have is because they have shifted 10 percent to the providers. We do all the work for HCFA now. All that work is done by the providers through layers and layers of regulation and rules and paperwork.

Every Medicare patient who walks into my office today is asked by the nurse beforehand, "The doctor may want to do something that is not a covered benefit. Here is a sheet. You can't sign this yet. He has to make sure he remembers to ask you to sign this if he does anything to you. So, will you help the doctor remember?"

We have another piece of paper that goes with every Medicare patient now, so that in case I order an EKG that they may not think was indicated, I have a patient sign it so that if Medicare doesn't pay for it, they can be responsible for it.

The whole idea to say that HCFA has any resemblance-Mr. Hash could not even answer the questions about his own organization. Nobody in HCFA knows all the rules, and they will all readily admit it, including the administrator.

So, to claim that we have this wonderfully efficient organization, that it is administering Medicare, to me is absurd. They are not efficient. They create inefficiency. They have raised costs. I want to make one other point. There is no question that a large portion of the solvency, and remember, when we say "solvency," we are talking about the time when the Medicare part of the trust fund runs out of money.

In 2012, it starts paying out more than comes in. One of the major reasons it is doing this is because we are collecting a whole lot more Medicare money because a whole lot more people are working at a whole lot higher salaries. It never goes away. It doesn't matter how much you make in this country, you are still going to pay 2.8 or 2.9 percent of what you earn.

So, as we get all hot and bothered about how well we have done, what we have really done is what Dr. Waller said. My partners are scared to death. They never code adequately on Medicare because they never want to be accused that they over billed Medicare because they don't want to go through all their charts for an audit and lose their Constitutional rights to a government which I consider an agency that is worse than the IRS ever thought about being in terms of the way they treat physician-providers and hospitals.

If you don't think that is true, go to a hospital and ask them to show you how many people are there to provide the record documents for Medicare. In my hospital that has 1,000 employees, 130 employees are there because Medicare has made them be there to document what they are doing.

The assumption is that you are doing it wrong and you have got to be able to prove it right, rather than you are innocent and we are going to prove that you did it wrong.

Until we change that philosophy at HCFA, until we assume that people are going to do the right thing, and catch the ones who are doing it wrong, we are going to continue to have people running away from Medicare.

In my community alone, today, Medicare patients can't find a physician to care for them. They cannot. It is not money. They don't want the hassle any more.

You know, I don't want this hearing to end with anybody thinking HCFA is doing a great job. Because the job they are doing is gumming up the works in terms of health care.

Are we doing great for patients on Medicare? Are we doing better? Yeah, but HCFA isn't doing any better. We are doing better because physicians and providers out there are sacrificing their own income to make sure people are careful.

People aren't getting stents-the other point, Mr. Fleming, and the point that wasn't made is we had a whole lot of people who ended up having "cabbages," coronary artery bypass grafts, had their chest opened, of which about 5 percent die, because the government wouldn't approve a stent. So they are having an invasive procedure that cost Medicare a ton more than having the stent put in.

So to say that HCFA is doing a great job, it fits with what goes on in Washington. It tells you that we have no connection with reality, the real world.

I want to ask one other question. If the error rate allows $13 billion in errors now, and we are proud of that, we are down to 7.9 percent, what is going to happen to get it down the rest of the way.

Mr. MANGANO. One of the things that we have encouraged HCFA to do is far more education, providing more services to the Medicare community to help them work their way through the process. They need to do a better job explaining what the regulation are.

Mr. COBURN. Okay. Let me ask you a question. Did you hear my comment to Mr. Hash about why don't we just change it and just go by blocks of time?

Mr. MANGANO. Yes, I did hear that.

Mr. COBURN. What is wrong with that?

Mr. MANGANO. You know, when you ask an Inspector General what you would like to have, we would like to have as simple a

process as possible because it is real easy to enforce the law. I think it is a novel approach.

Mr. COBURN. You know, I can only work 24 hours a day. If I am billing Medicare for more than 24 hours, there is something wrong there.

Mr. MANGANO. Now, you would be surprised, but we have had physicians who billed more than 24 hours in a day.

Mr. COBURN. I understand that, but I would also contend with you that the vast majority of physicians in this country sacrifice their family, sacrifice their social life, sacrifice most of the things because they are seeing patients 12 to 15 hours a day.

The fact is that the last thing you want to do is cheat Medicare. What they want to do is dedicate their lives to taking care of folks.

The assumption that has come about is that physicians are at a higher rate of defrauding the government in terms of Medicare. Mr. Norwood and I had a conversation and the fact is that I will bet on physicians as compared to the Members of the Congress any day in terms of integrity, honesty and work ethic.

For us to allow them to be painted as something less than working and caring for their patients I believe is wrong.

So, why hadn't that come back from the Inspector General saying change this stupid system where it is something manageable and measurable?

Mr. MANGANO. We have on a number of occasions recommended to HCFA areas where they could simply any number of different kinds of——

Mr. COBURN. What has been their response?

Mr. MANGANO. One of the areas that we were particularly strong on was laboratory services. For example, back a number of years ago we found it difficult to understand why some laboratory tests would be covered in one part of the country and not in other parts.

You already had that discussion so I won't go into that. We recommended that they try to create more of a uniform policy across the United States so people knew what was going to be covered.

I know they did make some changes but I don't think they went as far as they could have gone.

Mr. COBURN. Would you be so kind as to give us other recommendations that you have made that they have not done?

Mr. BILIRAKIS. Well, I don't know that we should. Can you respond to that in writing, sir?

Mr. MANGANO. Sure. We will go back and look through it.

Mr. BILIRAKIS. You are very helpful here. But in a 5-minute questioning and your 5-minute opening statement, that is just scratching the surface, barely.

So, we would very much appreciate information from you that might be helpful as we take a look at the overall picture. I have already mentioned a number of areas to Dr. Coble.

How much time, sir, do you think it will take for you to respond regarding my questions?

Mr. COBLE. A week.

Mr. BILIRAKIS. Mr. Mangano, Dr. Coburn's question?

Mr. MANGANO. I think we could probably do that in a week.

Mr. BILIRAKIS. Let me just ask Mr. Fleming. Mr. Fleming, it may not be a bad idea if, rather than do it now, if you can respond in

writing to the problems that HCFA seems to be having with your category approach.

Mr. FLEMING. Yes.

Mr. BILIRAKIS. From what I understand, you all have done everything you possibly can to get their attention regarding recommendations that you have made.

Mr. FLEMING. Mr. Chairman, there is nothing in the statute that says you cannot use categories.

Mr. BILIRAKIS. But they insinuated that that was the case, if you will recall. So, please respond in writing to us.

Mr. FLEMING. I will do that.

Mr. BILIRAKIS. Ms. Gottlich, I don't know if you had anything you wanted to offer, but by all means, please feel free to do so.

Dr. Waller, I know you put up your hand. Did you want to make a statement?

Mr. WALLER. Just to comment on Dr. Coburn's questions and throughout the hearing, the hearing is all about the patient. Quality of care if the problem, not managed care. We have overuse and misuse and under use of services and we need to put a system together that will allow quality to improve.

I just will make one final comment about the private marketplace. We don't have one. We don't have a truly competitive marketplace and the reason we don't is because fully a third or more of the payments for medical services which come from our government, and we appreciate those, have been under price control since 1984, and in a true competitive marketplace, you can't have one when price controls are present at that level.

So, I think that what we need is a system where the entitled consumer of health care is the valued conscious consumer of health care. When that occurs, we won't need to mandate all the rights that we are trying to mandate.

Thank you very much.

Mr. BILIRAKIS. Before I yield to Mr. Brown, Dr. Coburn made the statement comparing, I guess, the integrity of the members of the medical profession and Members of Congress.

Well, I think the integrity of the medical profession is really up there. There is no question about it. My son is one of them and he is a primary care physician, not a specialist.

But, I sort of disagree in a sense. I think Members of Congress in general are the most intelligent, basically one of the most ethical people I have ever seen. There are rotten apples in every bushel. God knows the medical profession has its share, too. I have experienced it.

Having said that, Mr. Brown.

Mr. BROWN. None of them are on this committee, Mr. Chairman.

Mr. BILIRAKIS. No, not a member of this committee.

I just have one quick question for Ms. Gottlich, if I could ask her a question. One advantage of Medicare is the rules of the program are set out in statutes and regulations and they are the same for all patients.

Patients in the private sector, as you know from them calling you, have different rules depending on their health plan and equally important, these rules are not always disclosed by the health insurers.

What difference does that make if the patient knows what to expect from a health plan? Do patients expect, do they think Medicare will treat them more fairly than private insurance?

Ms. GOTTLICH. It makes a very big difference. And it makes a very big different for those of us who represent them. If someone comes to me and they say, "I was denied by Medicare for dental coverage" I can say, "Medicare doesn't cover dental coverage except in limited circumstances" because I know what the rules are.

If they come to me in a private health insurance plan, I have to get the plan, which is first a very big hassle and delaying technique. Then I have to figure out where it is in the plan. Then I have to figure out where the appeals procedure is. That varies with each plan.

Under Medicare there is a set appeals procedure. So, the process takes a lot longer for private insurance to try to figure out where you are and what you get covered when you have terms like skilled nursing care and they are not defined anywhere in the private health plan.

Then you have to go look at State law and you have to make arguments relating to Medicare. It is really very difficult and you also get in the same context, different interpretations as you do with different carriers.

At least in the Medicare regulations you have a definition of what skilled nursing care is.

Mr. BROWN. Do patients expect that Medicare will treat them more fairly than private insurance?

Ms. GOTTLICH. Yes, I think that they do. I think for the most part they think that things will be done in a routine way. They will get the certain kind of same standard notices that they see from time to time. If you are on a private health insurance plan it is going to differ from each, insurer to insurer.

Mr. COBURN. Would the gentleman yield?

Mr. BROWN. Sure, I will yield.

Mr. COBURN. I just wondered, Ms. Gottlich, would it be your opinion that the government ought to run all health care that way?

Ms. GOTTLICH. I would like to see certainly Dr. Norwood's Patient Bill of Rights.

Mr. COBURN. But that is not what this hearing is about.

Ms. GOTTLICH. No, it is not what this hearing is about.

Mr. BROWN. I asked her that question, in her defense.

Mr. BILIRAKIS. Why don't we get into those better than 13,000 claims. What are those?

Ms. GOTTLICH. They run the gamut from every kind of Medicare case that you can think of. The majority of them are denials or terminations of home health care, skilled nursing care and hospital care under Part A. But they will also be for devices and technologies and services under Part B as well. The issue would be whether the service is necessary.

Ms. GOTTLICH. We wouldn't take them if they were not meritorious. Let me explain what that 13,000 means. The 13,000 is cases at a variety of different levels in the appeals system. The claim comes to us. We do an initial analysis of whether or not we are going to take the case.

If we decide we are going to take the case, it then goes through reconsideration. Once it goes through reconsideration, we decide again whether we are going to appeal to the administrative law judge. If it gets to the administrative law judge and we lose, we make this winnowing out.

We are not going to pursue a case that is not worthwhile for a number of reasons. One, it is fraud on the system, and No. 2, we have limited resources as well.

Mr. BILIRAKIS. Well, I appreciate that. Are these all fee-for-service type cases, would you say?

Ms. GOTTLICH. No. They are fee-for-service and managed care.

Mr. BILIRAKIS. What would you say is the percentage?

Ms. GOTTLICH. The overwhelming majority of our cases are fee-for-service cases because a lot of our clients are duelly eligible for Medicare and Medicaid so there are situations where the Medicaid has paid first and we are trying, because Medicaid is the payer of last resort and we are trying to get Medicare payments where it is appropriate to do so.

Mr. BILIRAKIS. Is there anything further from the subcommittee?

Mr. BROWN. Thank you everyone.

Mr. BILIRAKIS. Yes, we appreciate your patience sitting through the very lengthy first panel. You know, you have been an awful lot of help. You will be even that much more of benefit to what we do here if in fact you will submit, even if you haven't received a particular question, to us any suggestions you may have regarding the "onerousness of HCFA," if you will.

I don't think anybody has thrown stones at HCFA in terms of their lack of wanting to do the job well. But we also have heard these horror stories of the paperwork and the over-regulations. So we need your help in that regard.

Thank you very much.

The hearing is adjourned.

[Whereupon, at 1:40 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

The American Association of Orthopaedic Surgeons (AAOS), representing 16,000 Board certified orthopaedic surgeons, appreciates the Subcommittee on Health and Environment of the Committee on Commerce for holding hearings to address Medicare's regulatory burden on physicians. We would like to offer our perspective on this issue and welcome the opportunity to work with the Subcommittee as you examine the management of the Medicare program and the levels of burdens placed on physicians through Federal regulations.

The AAOS shares the Federal government's concern about intentional acts to defraud the Medicare program. There is no question that every reasonable effort needs to be made to eliminate true waste, fraud and abuse from the Medicare program. However, fraud and abuse regulations should not be so complex and so difficult to follow that the honest, vast majority of physicians wind-up making unintentional errors. We also do not believe that these regulations should be so burdensome that physicians and their staff end up spending more time trying to comply with them and less time taking care of patients.

Navigating the complex maze of fraud and abuse regulations has become a nightmare for physicians, burying them in an unprecedented sea of "red tape" and administrative hurdles. More importantly, these regulations are threatening access to quality health care services for Medicare beneficiaries because physicians have less time to spend with patients.

Federal regulatory requirements and their enforcement frustrate physicians on a daily basis. Time once spent treating patients is now being spent completing mandatory documentation and billing requirements, as well as other regulatory obliga-

tions. Not only are physicians spending more time away from treating patients, but also, the Health Care Financing Administration's (HCFA's) burdensome and complex requirements are making it difficult and sometimes impossible for doctors to accept new Medicare patients. In some cases, physicians are leaving the medical profession altogether. Moreover, physicians are spending more time second-guessing the regulators and the enforcers about whether they should be providing a particular service, instead of—and without hesitation—doing what is in the best interest of the patient.

The biggest problem in this area of Federal regulation is that there is no "bright line" as to what constitutes "illegal" or improper conduct. The presumption running though these regulations is that physicians are violating the law and are guilty of defrauding the government, unless they can document otherwise. We need rules and regulations that are understandable, fair and, most importantly, provide clear guidance about what constitutes proper and improper conduct. Instead, we find the current environment to be confusing and ambiguous—where law-abiding doctors are placed in an increasingly hostile and adversarial relationship with the government.

In an effort to ensure that the regulatory requirements placed on physicians do not adversely affect access to quality patient care, the AAOS supports remedies that are consistent, predictable and clearly understood by physicians. It is our hope that through oversight hearings, we will be able to:

- Simplify and clarify the regulatory requirements placed on physicians;
- Address the broad latitude HCFA has taken in interpreting its regulatory authority;
- Examine the documentation requirements placed on physicians to determine if they are achieving their intended goals;
- Examine HCFA's medical review process and explore how the current process places the onus on physicians to show that they are complying with HCFA's requirements without adequate due process protections;
- Restore the physician-patient relationship to one where there is trust between parties;
- Encourage cooperation between the government and physicians rather than continue the current adversarial relationship; and,
- Apply regulations in a consistent, clear and understandable manner.

As Congress tackled the enormous task of reforming the Internal Revenue Service, these hearings begin the effort to improve HCFA and its administration of the Medicare program. By taking this step we will ensure that a reasoned approach emerges that will reduce the incidence of real fraud and unintentional errors while freeing up physicians to do more of what they were originally trained to do—take care of patients.

The AAOS has identified a number of specific issues where congressional oversight is necessary.

Aggressive and Overreaching Authority by Federal Agencies

We believe HCFA and the Department of Health and Human Services has overstepped their authority in their efforts to eliminate Medicare fraud and abuse by using aggressive, overzealous enforcement techniques against physicians without sufficient evidence of intentional wrongdoing.

For example, the Anti-Kickback Statute was, in theory, intended to promote the integrity of the health care system. While it has achieved this goal, in practice, the statute also has stifled innovative business practices that could have saved the government money. The 1972 statute was originally enacted to address bribes and kickback arrangements in the health care arena. Congress broadened its scope in 1977 to address "any remuneration" giving the Office of Inspector General of the Department of Health and Human Services (OIG) great latitude in interpreting its mandate and applying this law to business arrangements far beyond kickback and bribes. While Congressional intent was to prevent unscrupulous behavior, the statute has allowed the OIG to develop a confusing patchwork of complex regulations and advisory opinions concerning, joint ventures, leases, discounted services, personal service contracts, that significantly limit innovation in the integrated health care delivery marketplace.

HCFA also has taken broad latitude in interpreting its authority by implementing initiatives such as the "Who Pays? You Pay." campaign. This initiative attempts to enlist Medicare beneficiaries to inform on their physicians if they suspect their Medicare bill is fraudulent. Unfortunately, it has the serious potential to damage the physician/patient relationship by creating an atmosphere of distrust between the doctor and patient when an open and honest relationship is essential to effective care.

The OIG also recently unveiled its "Compliance Program Guidance for Individual and Small Group Physician Practices." This compliance program significantly raises the stakes for hardworking and honest physicians who currently make every attempt to comply with the law. Not only is the creation of a plan extremely labor intensive and expensive, it has the potential to shift the burden of proof to the physician.

The OIG has stated that it only prosecutes offenses that are committed with actual knowledge of the falsity of a claim, reckless disregard or deliberate ignorance of the truth or falsity of a claim. But by having an effective plan in place, virtually any innocent billing error or mistake could trigger OIG action or prosecution since a compliance plan in place will indicate that the physician knew or should have known that a certain activity violated the law. While OIG officials may claim that the presence of an effective compliance plan will be taken into consideration if punitive action is necessary due to alleged billing errors, evidence of a compliance plan could be interpreted to transform the knowingly and willfully standards of law into per se violations.

Complex and Contradictory Regulations and Increased Documentation Requirements

Many rules promulgated by HCFA are so confusing that they convey no clear indication of how the agency will deal with a particular practice leading physicians to be unsure about their duties and liabilities. We need better guidance to negotiate the complex maze of regulatory requirements.

For example, orthopaedic surgeons in the AAOS have been perplexed about the in-office ancillary services provisions of "Stark II" and HCFA's proposed rule requiring suppliers of durable medical equipment (DME) to obtain a surety bond. The proposed rule to "Stark II" excludes DME from the in-office ancillary service exemption, thus prohibiting the disbursement of DME in-office. Yet, under the surety bond proposed rule, HCFA states that physicians will not have to meet the DME surety bond requirement—if they are providing these items incident to patient care. It seems that HCFA is recognizing that DME is distributed by physicians in-office, even though the proposed rule to "Stark II" seems to prohibits it.

Thus, it appears to the AAOS that HCFA has two proposed rules that have contradictory statements. Are physicians in the various practice arrangements allowed to disburse DME incident to patient care without violating the ″Stark II?″ Do physicians need a surety bond to disburse these items in office? If they have a surety bond, and are designated as suppliers by HCFA, then how is "Stark II" applicable?

Since DME is such an integral, customary, and appropriate part of patient care, commonly provided to patients as an in-office ancillary service, the blanket prohibition in "Stark II" makes little sense, and the AAOS would strongly urge both HCFA and Congress to revisit this issue, so physicians have clear guidance about the disbursement of DME.

In addition to this DME issue, the AAOS is greatly concerned about the enormous complexity of the proposed rule related to the physician ownership and self-referral statute known as "Stark II." The AAOS maintains that HCFA's proposed rule issued in January 1998 does not provide clear, unambiguous guidance for compliance. Instead, it has added even more confusion to what activities are permissible with regard to the ban on physician self-referral. While the AAOS is hopeful that the final rule for "Stark II" will address many of these concerns, Congressional oversight is necessary and legislative remedies may be appropriate to achieve Congress' intent and to provide clear guidance to physicians.

The AAOS also is concerned with HCFA's increased documentation requirements for physicians when they perform and bill for evaluation and management (E&M) services. There seems to be a presumption that physicians who make errors in coding these services on Medicare claim forms are "guilty" of defrauding the system—unless they can prove otherwise. Even though HCFA has attempted to ease these documentation requirements, physicians still can run afoul of the rules and regulations.

For example, when coding modifier-25 is used with CPT codes for E&M services, they may trigger an audit even though their usage is perfectly legitimate and saves on paperwork and reduces the administrative burden for both physicians and claims reviewers. Modifier-25 is used in billing when additional services are provided to beneficiaries beyond the services described by E&M codes. This modifier was intended to reduce the documentation requirements imposed on physicians. However, because their usage may trigger an audit, physicians are forced to submit claims for each additional service supported by separate documentation for each service in order to avoid triggering audits.

In sum, confusing, complex regulations and documentation requirements present the physician with a maze of nearly incomprehensible rules for which non-compli-

ance may be inevitable even for those with the best of intentions of filing appropriate claims for services provided under the Medicare program.

Limited Due Process

Through pre-payment reviews and post-payment audits conducted by carriers, HCFA engages in audits of physicians on a random basis without probable cause. Even while HCFA acknowledges that much of what is uncovered in these reviews and audits are simple billing mistakes, lack of documentation or disagreement on treatment procedures, claims submission has become legally treacherous for physicians. Fear of triggering an audit has actually led to "downcoding"—a practice of underbilling Medicare for services provided to Medicare beneficiaries—in order to reduce the chance of triggering an audit.

Under the current scheme, physicians are exposed to purely random audits without probable cause and without knowing of the criteria used by HCFA or its carriers to make its determinations. And once an audit is triggered, physicians are subject to recoupment of alleged overpayment, penalties and interest through the use of extrapolation techniques. The only remedy for physicians once they receive an overpayment notice is to open their practice to a statistically valid random sampling of claims to contest HCFA's findings, which, by HCFA's own admission, is very disruptive to a health care practice. Physicians would like the government to define the rules, parameters and standards that outline the scope of these audits as well as clearly identify the criteria used to trigger audits.

Conclusion

The vast majority of physicians are honest and dedicated individuals who make every attempt to comply with Medicare's complex requirements. Their primary goal is to provide the highest quality care to their patients. Physicians understand the need for regulations in the health care system. However, the rules that they are being asked to comply with and support should be presented in a clear and precise manner so that they can practice their profession without fear of punishment because they could understand what was expected of them.

The AAOS is very pleased that the Congress is taking an active role to ensure the Medicare program functions efficiently for all stakeholders. Through Congressional oversight hearings, we will be able to examine what is working and what is not working in the current system.

As Congress moves forward, the AAOS has several recommendations that would address many of physicians' concerns:

- Simplify and clarify HCFA regulations related to the Medicare program so that they are less burdensome and more easily understood by physicians;
- Promote a more accommodating environment between physicians and Federal agencies through more collaborative education efforts;
- Establish adequate due process protections and a threshold requirement of probable cause when investigating health care professionals providing services under the Medicare program;
- Develop mechanisms to hold HCFA and other government agencies accountable for oversight and review activities;
- Delay when a law goes into effect, as well as all enforcement activities, until final regulations are issued;
- Eliminate the prohibition of administrative or judicial review of Medicare payment and review methodology; and,
- Eliminate the "scoring" of budget savings as a result of fraud and abuse activities. As long as the pursuit of fraud is viewed as a "bounty" or revenue raising activity, cost-containment measure, or a way to expand program benefits, overzealous investigations of physician coding and billing activities will continue.

Again, we appreciate the opportunity to share with the Subcommittee our concerns about the unnecessary burdens currently placed on physicians by the activities of HCFA and the OIG, and we look forward to working with you to ensure quality patient care under the Medicare program.

PREPARED STATEMENT OF STEVEN M. MIRIN, MEDICAL DIRECTOR, AMERICAN PSYCHIATRIC ASSOCIATION

The American Psychiatric Association (APA), the medical specialty society representing more than 42,000 psychiatric physicians nationwide, is pleased to submit this statement to the Subcommittee on Health and Environment at its hearing on the management of the Medicare program by the Health Care Financing Administration (HCFA). First and foremost, Mr. Chairman, the APA commends you and the

Subcommittee on Health and Environment for your concern about our patients and profession by conducting today's hearing.

We acknowledge at the outset that the task of day-to-day operational management of Medicare must be daunting. By its own statement, HCFA—through Medicare, Medicaid, and the new children's health insurance program (SCHIP)—is the largest health insurance administrative entity in the nation. It will process almost a billion claims submitted by some three-quarters of a million physicians, non-physician health professionals, hospitals, and other health providers and suppliers. On the Medicare side alone, HCFA is the insurance company for 39 million elderly and disabled beneficiaries.

The sheer size of the Medicare program alone is staggering. Nor is Medicare a static target. As you know, the program is subject almost every year to numerous legislated changes (335 in the Balanced Budget Act of 1997, according to HCFA), including in recent years the development of extraordinarily complex system for paying physicians (i.e., the RBRVS-based fee schedule). Budget-driven priorities have led successive Administrations and Congresses to farm the statute for short-term savings necessitating complex changes in payment rules, or for longer-term changes in program administration (i.e., stepped-up efforts to target program fraud and abuse).

Each of these developments requires the promulgation through public process of new regulations and the development of a variety of complex instructions to HCFA contractors (i.e., Medicare carriers and fiscal intermediaries) on how to administer claims on a day-to-day basis. Thus, it is small wonder that as the covered population and covered services have grown, and as the various mandates passed on to HCFA by successive Congresses and Administrations have also grown, the Medicare program itself has become extremely complex and, from the perspective of the physicians represented by the American Psychiatric Association, increasingly unwieldy, unresponsive, and in many cases apparently hostile to the physicians who provide medically necessary care to our patients who are Medicare's beneficiaries.

APA would like to associate itself with the excellent remarks presented to the Subcommittee by Yank D. Coble, M.D., on behalf of the American Medical Association. We also believe that the Subcommittee would be interested in the specific problems APA members—and their patients—are now experiencing with the Medicare program. This statement will focus on these issues.

On a general basis, APA as the national medical specialty for psychiatrists is increasingly hearing grave concerns from our physicians in the field that they and the patients they serve feel under siege by a Medicare administrative operation that is too-often unresponsive, insensitive, and hostile. We believe that much of the problem stems from the autonomous nature of HCFA carrier operations.

As you know, Medicare covers services that are medically reasonable and necessary, entitles beneficiaries to these services, and requires appropriate documentation for claims filed. Medicare uses roughly twenty-four private contractors (the carriers) to administer claims filed under Part B of the program.

As contractors, carriers are subject to specific contractual requirements from HCFA that govern their responsibilities. Despite the fact that Medicare is a federal program with supposedly uniform national coverage and payment criteria, carriers in fact are given considerable autonomy and flexibility in their administration of Part B. For example, carriers are left to develop their own local medical review policies (LMRPs). The LMRPs are primarily a program integrity tool to specify criteria to determine whether a service is covered and to set standards for determining whether a covered service is reasonable, necessary, appropriate. The LMRP is not supposed to restrict or conflict with national coverage policy.

Too often, however, the LMRPs provide the means for widespread variation between carriers in the treatment of claims common to all carriers. This is particularly true of psychiatric services, where services defined as reasonable and necessary for beneficiaries in one carrier jurisdiction are denied as not being reasonable and necessary in another. This results in two major distortions of what should be a national program. First, patient access to identical services varies from carrier to carrier. Second, documentation requirements imposed on physicians for identical services vary from carrier to carrier. Taken together, these two important problems can and do result in reduced access to care for our patients and increased hassles for psychiatrists.

General carrier-related problems and anomalies associated with psychiatric services include the following:

- Alzheimer's Disease Coverage: The Medicare Carrier Manual stipulates that Alzheimer's patients are entitled to psychiatric services. A number of carriers, however, have been routinely denying any psychotherapy services for patients with a primary diagnosis of Alzheimer's disease, no matter what stage of the progres-

sively degenerative disease the individual patient is in or how minimal their cognitive impairment may actually be.

- Drug Management: Pharmacologic management (CPT-90862) is a service clearly covered by Medicare. APA review of carrier LMRPs shows widespread variation from the AMA's CPT manual that serves as the descriptor for the service.
- Family Therapy: This is another service clearly covered by Medicare, but APA members report that some carriers routinely deny all claims for the service, even when full documentation is provided.
- Review Triggers: Medicare's coverage of outpatient psychotherapy services is not subject to annual visit limits. Increasingly, however, carriers are developing LMRPs that subject all claims above a certain number (typically 20) to intensive review (in some cases 100% review). This creates a major administrative hardship for psychiatric physicians who often practice in a solo office environment and is a significant detriment to quality patient care.

Real-world examples of carrier specific issues include the following:

- In New York, the carrier, Empire, is routinely subjecting 100% of claims for CPT codes 90846 and 90847 (family therapy with and without the patient present) to prepayment reviews. This occurs every time these codes are submitted, even when Empire has approved the same service for the same patient by the same psychiatrist the month before.
- In Massachusetts, Maine, New Hampshire, and Vermont the carrier, NHIC, has been routinely denying medical family therapy claims, even though family therapy is clearly a benefit covered under Medicare. I note that psychiatrist appeals of the denials are usually decided in favor of the psychiatrists.
- In Arkansas, one of our members reported that his hospital had started a partial hospitalization program (PHP) at the urging of managed care organizations who told them frequently that patients were not critical enough for acute hospitalization but would be appropriate for partial hospitalization care if the hospital would establish a PHP. Less than a year after the hospital instituted its partial hospitalization program they were forced to shut it down because the Arkansas carrier decided to restrict all PHP care in response to fraud committed by a single mental health center in Arkansas that had contracted with an out-of-state company to manage their partial hospitalization program. While it certainly may have been appropriate to shut down the offending operation, it should not have resulted in the effective shutting down of every legitimate partial hospitalization program in the state as well.

In addition to the carrier-specific anomalies cited above, there appear to be general problems in the ways in which HCFA identifies potential problems within the Medicare program that adversely affect psychiatric services to patients. For example, we understand that HCFA uses "BESS" data (Part B Extract and Summary System data) to flag anomalous code usage and notify carriers that code usage within their charge locality is at variance with national averages, and to instruct carriers to develop LMRPs to respond to the variance.

Yet there seems to be no effort made to determine why the variance exists. It may well be that physicians in one state are encouraged by the carrier to use one code, while those in another are encouraged by their carrier to use a different code. Or it may be that a few individual physicians or other health professionals are outliers, using a disproportionately large share of the codes within a carrier's locality. Thus, coverage policies affecting thousands of physicians and the patients they serve seem to be made on the basis of abstract statistical data analysis, not on the basis of a determination that a specific problem exists.

Psychiatrists' problems with Medicare are not confined to carrier interface. Under current law, Medicare beneficiaries are required to pay a discriminatory 50% copayment for outpatient psychotherapy services. As a result of the 1990 budget law, Medigap insurance policies are supposed to cover the 50% copayment, but 10 years later, we continue to hear from psychiatrists who are having difficulty in persuading Medigap insurers that they are in fact liable for coverage of the 50% copayment.

In another example of how HCFA policy-making can have a sweeping impact on physicians, in July 1999, HCFA released an unannounced and complex new rule establishing a new "Patients Rights" condition of participation for Medicare and Medicaid hospitals. Included within the patient's rights is a series of provisions governing the use of seclusion and restraint of patients in acute medical and psychiatric settings. These sweeping standards amount to the imposition of untested standards of clinical care by federal regulatory fiat.

Issued as an interim final rule, the seclusion and restraint standards were put in force on 30 days notice (i.e., they were enforceable as of August, 1999) without benefit of prior public comment or field testing. A year later HCFA has still not issued a final rule, nor has it responded to the thousands of comments from psychia-

trists, other physicians, and hospitals, all of whom have pointed out major clinical problems with the interim final rule.

Despite the fact that the rule affects every Medicare/Medicaid hospital and imposes burdensome and sweeping patient care requirements that invariably will affect hospital staffing and require more intensive patient interaction per capita, the interim final rule asserts that costs associated with compliance will be minimal. This is palpably untrue, but HCFA has failed to respond to our requests for substantiation of its cost analysis.

APA, AMA, and the hospital community have exhausted all efforts to engage HCFA in a meaningful dialogue that might result in the development of clinical consensus. Yet the standards remain in force, despite widespread and thoughtful disagreement from expert clinicians, and despite compelling evidence that some hospitals may not be able to comply with the standards, thus risking decertification. At a minimum, the rules represent a substitution of the inflexible judgment of a bureaucrat for the independent clinical judgment of the physician responding to the needs of his or her patient.

Ironically, we believe that the rule will result in reduced access to needed inpatient psychiatric care, as hospitals may screen out patients with a track record that suggests the likelihood of restraint and or seclusion. Such patients will more than likely end up in the forensic system where they are much less likely to receive the care their mental disorders require. This will be the unhappy result of the establishment of clinical practice standards by bureaucratic fiat, and furthers HCFA's image as unthinking, unresponsive, and capricious.

Finally, our members in the field tell us that a major problem with Medicare is a lack of responsiveness and accountability throughout the system. For example, carriers have told our members that Carrier Advisory Committee meetings are not subject to federal sunshine requirements, and thus that the CACs are under no specific obligation to open up their meetings to the concerned physicians and their representatives who are directly affected by CAC deliberations. In addition, there is widespread reluctance throughout the system to put information and interpretations about claims, particularly about denial policies, in writing. Thus, physicians are forced to rely on oral statements from carriers which cannot subsequently be used to justify future claims.

Mr. Chairman, to sum up, we believe that HCFA has an unenviable and complex job of administering the largest health insurance program in the United State. Psychiatrists, as any group of physicians, are interested only in the provision of medically necessary care to our patients. We would welcome the opportunity to work in partnership with Congress and HCFA to craft common sense solutions to Medicare's myriad operational problems with the object of improving patient access to care.

To that end, we make the following recommendations on behalf of our patients and our profession:

1. HCFA should conduct a systematic review of carrier operations with an eye to removing widespread variations in coverage and review practices by carriers. There is no justification for one carrier to routinely reject services that another carrier routinely covers.
2. 100% claims review practices effectively constitute carrier harassment of physicians and should be halted. If there is a specific problem with a specific code, HCFA and the carriers should work with local and national physician organizations to understand first if there is in fact a problem and second to craft a solution to the identified problem.
3. HCFA should follow administrative procedures. We echo the AMA's recommendation that HCFA should be required to conduct accurate regulatory impact and cost analyses and to fully account for the burden of complying with a proposed regulation before putting them in force.
4. HCFA should conduct nationwide physician education workshops. If, as HCFA suggests, there are widespread inadvertent claims submission errors, then it is logical that the errors stem from program complexity and lack of clear direction on how to properly file claims. Rather than assuming criminal intent, HCFA should acknowledge the necessity for widespread cooperative education of physicians and other providers.
5. Carriers should be required to provide explanations of coverage decisions and interpretations in writing in an understandable form. If physicians request guidance from carriers on how to file claims and which codes to use, the information should be provided in writing when requested. Carriers should not be allowed to avoid responsibility for the advice that they give to physicians, nor should physicians be subject to sanctions and penalties for following carrier guidance.
6. HCFA and the carriers should be instructed to reduce the adversarial nature of communications with physicians. Too often carrier communication with indi-

vidual physicians is predicated on the assumption that the physician is trying to defraud the Medicare program. To the contrary, the overwhelming majority of physicians are simply trying to render medically necessary care to their patients and to be paid with a minimum amount of bureaucratic hassle for the services rendered.

Thank you for the opportunity to testify.

ADDITIONAL COMMENTS FOR THE RECORD OF ROBERT R. WALLER, M.D., PRESIDENT EMERITUS, MAYO FOUNDATION AND CHAIRMAN, THE HEALTHCARE LEADERSHIP COUNCIL

I would like to thank you for inviting me to appear before your Subcommittee on Health and Environment to convey the views of the Healthcare Leadership Council on the negative effects that Medicare's complexity has on patient care. In addition, I would like to take this opportunity to comment further on some of the issues outlined in my testimony as well as some other related matters.

Mr. Chairman, many of the problems with the Medicare program, which were raised by members and witnesses alike during the hearing on June 27th, would be eliminated if the program was replaced with a private, value-based, competitive system. Under such a system, plans and providers would compete with one another to offer—not just the highest quality, most innovative care—but also the most user-friendly delivery of care. Competition between plans would ensure that the current Medicare program, which, as we heard during the hearing, has resulted in thousands of outstanding claims being reviewed by the Center for Medicare Advocacy, would be replaced by a program that offered a higher quality of care and more efficient coverage, in a less administratively complex program.

The current system has no incentives for efficiency. In the marketplace, competition is the mechanism by which we assure that prices are fair and that services are provided with maximum efficiency. Competition rewards informed consumers with lower prices and better quality of care, and punishes producers who are inefficient. Competition also rewards innovation and resourcefulness. Under the current Medicare program, price controls prevent prices from varying; thus, no incentive exists for either innovation by physicians or price-comparison by beneficiaries. By allowing providers to participate in a market reflecting actual economic conditions, they can distinguish themselves by competing for patients based on quality and value.

No one benefits—not the government, not the provider, and certainly not the patient—when providers must make the hard choice of whether to reduce their services to beneficiaries in the face of Medicare's misguided payment policies. Furthermore, beneficiaries would rather be welcomed by health care providers as valued patients and customers than be viewed as wards of a flawed and poorly conceived public program. Beneficiaries under a competitive value-based system would be rewarded tangibly for seeking value. The result of such a program will be a health care delivery system that is patient centered, not one that simply achieves a regulatory standard.

In sum, price controls don't save, they *cost*—they cost us in lower quality, less innovation, and wasted energy. Patients, providers and taxpayers all suffer because the distortions have become so great as to become the central features of the system.

False positive projections of a healthy trust fund reduce the incentive for reform. Unfortunately, estimates regarding the integrity of the Medicare program, provided in annual updates on the program's date of insolvency, are not only delaying these much needed fundamental reforms, but do not accurately reflect Medicare's financial health. Without reform, the program is expected to face mounting pressures in coming years, arising not only from the rapid growth in the number of eligible people but also from increases in the cost of care per patient as medical technology advances and longevity of life increases.

Medicare trustees noted in their 2000 report of the Hospital Insurance (HI) trust fund that under a less promising, higher cost economy, Medicare bankruptcy could occur as early as 2012. By the trustees' own admission, projecting the health of the trust fund, even a short time into the future, can yield precarious estimates. The following are quotes from the 2000 trustees' report:

> "Without corrective legislation, the assets of the HI trust fund would be exhausted within the next 12 to 23 years under the high cost and intermediate assumptions. The fact that exhaustion would occur under a fairly broad range of future economic conditions, and is expected to occur in the not-distant future (under most scenarios) indicates the importance of addressing the HI trust fund's financial imbalance.

Today's booming economy means higher wages and more employment. For Medicare, this means that the 2.9% Medicare tax has applied to a much larger base of payroll in recent years. Employment taxes flowing into the HI trust fund dramatically increased by 19% over the past 2 years (from $112.7 billion in 1997 to $134.4 billion in 1999). These revenues cannot be depended on in the coming years. Besides the possibility of the economy slowing down, the number of people working and paying the Medicare tax will soon begin declining as baby boomers begin retiring in 2010. Once the baby boom generation has fully entered retirement by 2030, workers per beneficiary will decrease from the current 4.0 to 2.3. While the baby boom population currently pays 57.7% of all payroll taxes, in thirty years, that number will drop to less than 2%.

Growth in Medicare spending since the BBA passed has slowed dramatically—much more so than was projected at the time of passage. Medicare spending increased by only 1.5% in 1998, compared with a projected 5.7% by the CBO when the BBA was enacted. And in 1999, for the first time in history, Medicare spending actually declined, dropping by about 1% instead of increasing by 5% as CBO projected. The substantial documented hardship these reductions have created demonstrate that continuing provider cuts in the current Medicare program cannot be depended on to sustain Medicare in the long run.

Just before the Balanced Budget Act of 1997 was passed, the Medicare trust fund was projected to run out of money in 2001. Immediately upon passage of the BBA, the Medicare bankruptcy projection was shifted from 2001 to 2007. What many do not realize is that barely two of these additional years were attributed to provider cuts. The majority of this trust fund solvency extension was due to the law's requirement that $174 billion in home health spending during the ensuing 10 years become a new responsibility of the Medicare Part B trust fund instead of the Medicare Part A trust fund as it had traditionally been.

While growth in home health spending has slowed dramatically since passage of the BBA—even more than was intended by the provisions therein (it grew on average by 21.9% a year from 1992 to 1997, and has slowed to -26.9% since the BBA)—relieving the Part A trust fund of this high-cost item has contributed significantly to the healthy *appearance of* the Hospital Insurance trust fund. However, transferring the responsibilities of the Part A trust fund to the mostly taxpayer-funded Part B trust fund is not an option for ensuring that the Medicare program can continue to provide high quality health care benefits into the future.

I emphasize these facts because, despite the trustees' warnings, I believe that these false positive reports of the HI trust fund's safety and soundness have indeed created a sense of complacency among policymakers. Indicative of this is the fact that earlier this year there was a marked change of course in the Medicare debate. While the year began with momentum to fundamentally reform Medicare, it is ending with the lesser goal of creating a Medicare prescription drug benefit, without comprehensively reforming the program. While we believe strongly in the need to provide seniors increased access to prescription drugs, the absence of reform, along with expanded benefits, will only serve to perpetuate the inefficiencies and complexities of the current program.

Since it appears that comprehensive Medicare reform will not occur in the immediate future, I will elaborate on a few areas that I believe could be addressed now.

The complications involved in the seemingly simple matter of Medicare payments has devolved billing errors into a morass of health care fraud. With no unity among the Department of Justice (DOJ), the Health Care Financing Administration (HCFA), and the Office of the Inspector General (OIG) in their approach to fraud prevention and investigation, voluntary disclosure among providers is not possible. Because there is a lack of clarity and understanding as to how the government will respond to entities who willingly come forward to report billing errors, any effort on behalf of providers to self-police is difficult, if not impossible.

For more than a year now, the Administration on Aging (AOA), HCFA, and the OIG, together with AARP and the DOJ, have been working to develop a nationwide outreach campaign to educate seniors on how to recognize and report Medicare fraud. However, no similar coordinated effort has been formalized by the government to help providers combat fraud and abuse.

As I mentioned in my testimony, the Healthcare Leadership Council (HLC) has formed an Industry and Government Partnership for Accountability Task Force, which consists of organizations representing every segment of the health care system. To date we have had several dialogues with these agencies regarding the intricacies of complying with Medicare regulations. The Industry and Government Partnership for Accountability plans to continue to undertake a significant effort to educate opinion leaders and top government officials and engage in a constructive effort to resolve this issue. The HLC believes that formalization of such a partnership,

with specific responsibilities to Congress to ensure clarification and consistency in the enforcement of Medicare rules, would help move the current system closer toward a model based on education and remediation.

The uncertainty of agency actions raises another concern that I believe deserves considerable attention. In my testimony I referred to the dramatic difference in the cost of compliance that HCFA and an outside organization estimated for the recently issued medical records privacy rule. *A formalized approach in preparing cost-benefit analyses would not only minimize the uncertainty that is associated with these rulemakings, but would also ensure that only those rules that maximize net benefits would be finalized.*

As you know, under Executive Order 12866, covered agencies are required to submit their "significant" rules to the Office of Management and Budget (OMB) before publishing them in the *Federal Register*. Agencies are also required to prepare a detailed economic analysis for any regulatory actions that are "economically significant." This economic analysis is to include an assessment of the costs and benefits anticipated from the action as well as the costs and benefits of "potentially effective and reasonably feasible alternatives to the planned regulation."

In January 1996, the Office of Management and Budget (OMB) issued "best practices" guidance on preparing cost-benefit analyses under the order. The guidance gives agencies substantial flexibility regarding how the analyses should be prepared, but also indicates that the analyses should contain certain basic elements and should be "transparent"—disclosing how the study was conducted, what assumptions were used, and the implications of plausible alternative assumptions.

However, GAO testimony submitted in June, 2000, "Procedural and Analytical Requirements in Federal Rulemaking", found that many agencies were not incorporating the best practices set forth in the OMB's guidance, including the failure to discuss alternatives to proposed regulatory action and assess the uncertainty associated with the agencies' estimates of benefits and/or costs. The GAO has recommended that the OMB's best practices guidance be amended to provide that economic analyses should (1) address all the best practices or state the agency's reason for not doing so (2) contain an executive summary, and (3) undergo an appropriate level of internal or external peer review by independent experts. Formally implementing these guidelines would create a critical threshold that would have to be met before potentially damaging changes are made to the Medicare program.

As long as the viability of a provider's business is subject to our ability to analyze and correct any "rosy scenario" assumptions used in government cost-benefit analyses, we have no choice but to divert our attention, energy and resources at the expense of patients.

Finally, the sacrifice in innovation spills over into the non-profit health care sector. That is why, Mr. Chairman, it is important to note that non-profit organizations—not just the for-profit community—support changes to the Medicare program that would rely on competition. These organizations, including the Mayo Clinic, treat patients who come from widely varying socioeconomic backgrounds and who are represented by private and public health plans. We all believe that fundamental changes are the only way to ensure that Medicare participants are not left behind the medical technology curve, but, rather, are beneficiaries of high quality, innovative, and patient-centered health care delivery system.

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
July 6, 2000

The Honorable TOM COBURN
House of Representatives
Washington, D.C. 20515

DEAR MR. COBURN: In my testimony on June 27 before the House Committee on Commerce, Subcommittee on Health and Environment, you asked me to provide you with some examples of recommendations that the Office of Inspector General has made to reduce the complexity of, or simplify the Medicare program.

Over the years, we have addressed the problem of complexity in our reports and in testimony before the Congress. Examples include our recommendations to:

- Require that all Medicare carriers use uniform prices when reimbursing outpatient prescription drugs.
- Equalize payments for ambulatory surgical centers and hospital outpatient departments when the same service is provided.

- Replace Medicare's complex and vulnerable cost-based reimbursement systems for nursing homes and home health, which tend to be very cumbersome and complex and include cost reports, with prospective payment systems.
- Eliminate differences in payments to physician offices when hospitals purchase physician practices.
- Develop product classification lists for orthotics not only to ensure that Medicare carriers can effectively verify that the correct amount is being billed for each item, but also to reduce the confusion suppliers may face in applying current orthotics codes.

In addition to our formal studies, we are sometimes called upon to provide advice during the course of day to day discussions about current Medicare payment, coverage, or administrative issues. In this context we also make recommendations to simplify Medicare rules. One good example is our advice to make Medicare coverage of laboratory services uniform among the Medicare contractors, recognizing that laboratory companies often operate across State and Medicare contractor boundaries.

Not only do Medicare policies need to be as simple as possible, but so do the systems used to submit bills and service beneficiaries and health care providers. The program needs to be understandable and easy to use by both. While adequate controls must be in place to ensure that only legitimate entities are paid for covered services, the program cannot be so complex and cumbersome that the deliverance of timely, quality care is hindered.

Therefore, in addition to making recommendations to simplify the program, we have conducted studies to obtain feedback from beneficiaries and health care providers regarding Medicare operations and program requirements. For example, we have conducted satisfaction surveys of:

- both fee-for-service and managed care beneficiaries;
- beneficiaries whose health maintenance organizations withdrew from the program;
- physicians regarding their use of and satisfaction with certifications of medical necessity for medical equipment and supplies; and
- physicians regarding their experiences with managed care.

In the same vein, we have conducted studies of the understandability of marketing materials for Medicare+Choice programs.

I hope these examples give you a flavor for the kind of work we do to help the Medicare program operate as smoothly as possible. It is sometimes difficult to balance the need for program controls with the need for simplicity, but we try our best to find ways to do so.

I hope this letter is responsive to your questions. Please feel free to contact me, or your staff may contact Helen Albert, Director for External Affairs at (202) 260-8610 if we can be of any assistance.

Sincerely,

MICHAEL F. MANGANO
Principal Deputy Inspector General

cc: The Honorable Michael Bilirakis, House of Representatives
The Honorable Sherrod Brown, House of Representatives

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
July 6, 2000

The Honorable CHARLES NORWOOD
House of Representatives
Washington, D.C. 20515

DEAR MR. NORWOOD: Enclosed is our response to the question you posed during the June 27th hearing about the composition of the savings the Office of Inspector General (OIG) reports to the Congress. Also enclosed is a chart by provider of the health care savings that OIG reported in Fiscal Year 1999.

If you have any additional questions, please call me or have your staff contact Helen Albert, Director of External Affairs, at (202) 260-8610.

Sincerely,

MICHAEL F. MANGANO
Principal Deputy Inspector General

Enclosures

cc: The Honorable Michael Bilirakis
The Honorable Sherrod Brown

SAVINGS REPORTED BY THE OFFICE OF INSPECTOR GENERAL

Question: You have reported savings resulting from OIG work of $12.6 billion in Fiscal Year 1999. What are these savings exactly and how are they realized?

Answer: The OIG measures its goal of having a positive impact on HHS programs in part by the savings that result from its work. These savings are categorized into three major types: (1) investigative receivables, (2) audit disallowances, and (3) funds put to better use.

Investigative Receivables—This category contains the monetary receivables attributable to our investigative activities. This category represents all fines, restitutions, settlements and recoveries generated by judicial or administrative action resulting from OIG investigations. Thus, criminal fines and civil judgements (whether levied by a Federal or State judge, or an Administrative Law Judge) are included in investigative receivables, as are voluntary settlement amounts and restitution orders. Total investigative receivables for FY 1999 were $407.7 million. Following is an example of this type of savings resulting from our work:

- A major provider of home health services and one of its subsidiaries entered into a $61 million global settlement, including approximately $10 million in criminal fines, related to, among other things, a series of transactions that the corporation made to disguise non-reimbursable acquisition costs as Medicare-reimbursable management services.

Audit Disallowances—In conducting audits, OIG routinely identifies improper expenditures and recommends that these "questioned costs" be recovered or redirected by agency management. Costs may be questioned because of an alleged violation of a provision of law, rule, contract, grant or other document governing the expenditure of funds; a finding that the costs were not supported by adequate documentation; or a finding that the expenditure was unnecessary or unreasonable.

After HHS management concurs with the OIG assessment that certain costs are questionable, those costs are disallowed, and the funds are recovered through direct repayment, offset or withholding. For FY 1999, a total of $251.5 million was identified for disallowance or redirection by agency management in response to OIG recommendations. As an example:

- The OIG reported to the Administration for Children and Families (ACF) that a State's retroactive claim improperly shifted juvenile justice costs to the Federal Emergency Assistance program (a former AFDC program that offered temporary financial assistance to eligible families experiencing an emergency) that ACF administered. The ACF agreed and notified the State that those costs were unallowable and requested repayment. The Department recently received a $17.3 million check from the State as repayment of the disallowed costs.

Funds Put to Better Use—The role of OIG is not limited to after-the-fact detection of fraud, waste and abuse; equally important is OIG's role in preventing such inappropriate expenditures. As a result of OIG audits and evaluations, recommendations are reported to management that frequently specify legislative, regulatory or administrative action. When implemented, they result in overall program savings. Management actions that could give rise to "reportable" savings include: direct reduction in budget outlays; deobligation of funds from agency programs or operations; avoidance of unnecessary expenditures identified in preaward reviews of contracts or grants; and costs not incurred as a result of implementing recommended improvements related to agency, contractor or grantee operations.

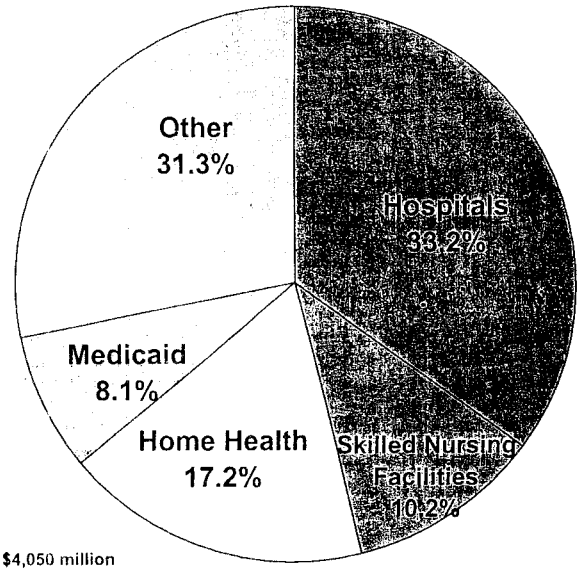
In calculating the amount of cost savings attributable to implementation of its recommendations to put funds to better use, OIG considers "implementation" to have occurred when the corrective action is actually accomplished. Thus, for example, savings will accrue only after the legislation is actually passed, when final rules are promulgated or when final action is taken by agency management. It is important to note that these savings are not calculated by OIG—instead the fiscal impact of legislative actions, for example, is estimated by the Congressional Budget Office in terms of annualized amounts that will likely be saved over a 5-year budget cycle. These CBO estimates serve as a neutral third-party valuation of actions corresponding to OIG work and are reported in Appendix A of the Inspector General's Semiannual Report to the Congress. Similarly, OIG reports regulatory and operational savings estimates as stated by the involved HHS agency (e.g., HCFA). In FY 1999, "funds put to better use" savings resulting from OIG recommendations totaled $11.9 billion. Following is an example of such recommendations implemented through legislative action:

- Medicare Secondary Payer Extensions—legislative provisions enacted as part of the Balanced Budget Act (BBA) of 1997—FY 1999 savings estimated by CBO totaled $1,700 million.

In a body of work of approximately of 40 separate audits and evaluations issued since 1984 and in a number of testimonies before the Congress, OIG recommended that legislation be enacted to (i) establish a centralized database of information about private insurance coverage of Medicare beneficiaries and (ii) extend the Medicare secondary payer (MSP) provision to include end stage renal disease (ESRD) beneficiaries as long as the individual has employer based coverage available.

Section 4631 of the Balanced Budget Act (BBA) of 1997 permanently provided into law that Medicare was the secondary payer for disabled beneficiaries in large group health plans and made permanent and extended Medicare as the secondary payer for ESRD from 18 to 30 months. It also made permanent the HCFA/IRS/SSA data match program.

$12.2 Billion FY 1999 Health Care Savings
(percent by provider)



Hospitals- $4,050 million
Skilled Nursing Facilities-
$1,250 million
Home Health- $2,099 million
Medicaid- $986 million
Other- $3,815 million, includes:
Medicare Secondary Payer
(extensions and questionnaire)
$2,125 million
Durable Medical Equipment
$505 million
Investigative Receivables
$324.1 million
Medicare Laboratory Reimbursements
$300 million

RESPONSES FOR THE RECORD OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

CONGRESSMAN BLILEY'S QUESTIONS AND ANSWERS FOR THE RECORD

1. Software has been developed that can enable a physician to use a hand-held computer to prescribe medication wherever he or she sees a patient. This software is capable of instantly alerting the prescribing physician to possible adverse reactions to other medication that a patient may be taking. In addition, this software enables physicians to electronically prescribe and transmit prescriptions to the staff in his office or to other pharmacies.

Q1a: Would you agree that the federal government should encourage the use of computerized prescribing and dispensing systems? If so, what steps can the Department take to take advantage of these systems?

A1a: We will publish regulations this year requiring the over 6,000 hospitals participating in the Medicare program to have ongoing medical error reduction programs that would include, among other interventions, mechanisms to reduce medication errors. In order to comply with this new regulation, hospitals may choose to implement automated pharmacy order entry systems, include automatic safeguards against harmful drug interactions and other adverse side effects built into the treatment process, or institute decision-support systems. We will not be mandating computerized prescribing and dispensing systems as the rule will allow providers the flexibility to determine how best to meet the requirements.

The Administration's Quality Interagency Coordination Task Force has addressed the use of decision-support systems and information technologies, such as the use of computerized prescribing and dispensing systems, as additional strategies to promote patient safety. The Task Force's report entitled: "Doing What Counts for Patient Safety," notes that, "although the success of health care informatics models is well documented and their applicability to patient safety is clear, they have not been widely adopted." To address this, the Agency for Healthcare Research and Quality (AHRQ) and the Center for Disease Control and Prevention will expand research efforts in the area of informatics to identify initiatives aimed at developing and evaluating electronic systems to identify, track, and address patient safety concerns. In addition, AHRQ, along with the Veterans' Administration, Department of Defense, the Food and Drug Administration and other members of the Quality Interagency Coordination Task Force will evaluate the effectiveness of automated physician order-entry systems in hospitals.

Q1b: While new technologies have tremendous potential for reducing medial errors, I am sensitive to the added costs associated with purchasing these products. Does current law provide a way for the federal government to help providers with the cost of acquiring this new technology?

A1b: Yes. Most Medicare payment systems are already updated annually to reflect changes in practice and new technology. We annually update payment systems for hospital inpatient, hospital outpatient, physician fee schedule, ambulatory surgical centers, and durable medical equipment. These payment system updates consider internal, external, and alternative sources of data in the decision making process. For example, we have an annual process for the physician fee schedule that relies on public input through the Federal Register comments and through the AMA Practice Expense Advisory Council and the Relative Value Update committees. These committees make recommendations to us on the appropriate inputs used in providing new medical services, in addition to making recommendations on refinements of inputs for existing physician services.

By considering the input of these outside sources, in combination with our own medical judgement, we adjust payment rates to reflect the cost of new medical services that may require the use of state of the art technology, such as that to reduce medical errors. For example, for inpatient hospitals, through an annual adjustment in the productivity factors in the operating and capital update frameworks, HCFA considers the cost increases and decreases associated with the employment of new technologies. Furthermore, HCFA recalculates the diagnosis related group (DRG) relative weights annually to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

Q1c: There are concerns that elderly and low-income patients in government health insurance programs may be less able to benefit from this new technology unless there are appropriate incentives to encourage physicians to bear the cost of investing in them. What thoughts have you given to the issue of providing appropriate incentives to assure that these computer systems are adopted?

A1c: As discussed above, most Medicare payment systems have a process to consider payment adjustments to reflect changes in practice resulting from new tech-

nology. The Department of HHS and other organizations such as the Medicare Payment Advisory Commission identify and monitor new advances and trends to be considered in the update process. Whether specific incentives for adoption of technology to reduce medical errors are needed is not yet clear, and there is evidence that providers, particularly physicians, are adopting this technology as part of their office practices without specific Federal incentives. There is a Secretarial initiative to improve quality of health care and reduce medical errors. At this time we are undertaking a number of activities in this area, and the best options for reducing medical errors are still being explored. We expect that the States also have similar goals for medical error reduction for the Medicare population. We have a great interest in reducing medical errors, and we look forward to working with you to examine this issue further as we continue to monitor the situation.

Q1d: My understanding is that state Medicaid programs pay dispensing fees to retail, mail order, or Internet pharmacies for filling prescriptions. Is the same fee paid for dispensing pre-packaged medication as for those that require special preparation or dosing?

A1d: We do not keep a data base on State drug dispensing fees. However, States have the flexibility to pay different "reasonable" dispensing fees based on the complexity of dispensing activity, such as compounding. In the State plan amendment approval process, we require States to explain and document the basis for such "reasonable" fees.

2. I have long been concerned that Medicare beneficiaries are not getting access to the best and most appropriate technologies and procedures. I understand that there are several processes that new technologies and procedures must go through in order to be made available to beneficiaries. The first process involves making specific coverage determinations about which medical procedures and products to make available to Medicare beneficiaries. However, I understand that simply covering a product or procedure doesn't mean that beneficiaries will actually have access to it, but that two other processes exist to establish a "procedure code" and then the appropriate payment category or level for the product. And even after coverage, coding and payment issues have been resolved, there still remain the basic mechanics of notifying fiscal intermediaries and carriers to go ahead and make payment.

Q2: Please explain how coverage, payment, coding, and intermediary/carrier operations are currently organized in HCFA. Please explain how HCFA ensures that patients get timely access to appropriate technologies, and how management coordinates the various offices at HCFA, as well as the central and the local carriers who are also involved in many of these processes.

A2: There are three levels of coverage and payment determination, each serving important functions in assuring that beneficiaries have access to appropriate technology. The vast majority of determinations are made on a case-by-case basis by our local contractors. Because most new technology involves only minor modifications to existing technology, these determinations are usually straight forward and rolled into existing coding and payment mechanisms. For new technology that is significantly different, our coding system includes generic "99" codes in each benefit category which providers can use to file claims. Claims with these codes are manually reviewed and priced. For new diagnostic and surgical procedures provided by hospitals and other facilities paid through prospective payment systems (PPS), no coverage determination is generally necessary as new technology is automatically folded into the appropriate diagnostic related group (DRG) payment category. (There is one exception; the new hospital outpatient PPS system includes a pass through for new technology.) Under the hospital inpatient PPS system, the actual impact of innovations on costs are reflected through charges that the facility includes on its Medicare claims that drive future classification recalibrations. These charges often show that new innovations lower overall charges by, for example, decreasing the number of days patients must remain in the hospital, even if the new technology itself costs more than what it replaced.

A second, formal level of coverage and payment determination is also carried out by local contractors when they develop "local medical review policy." These policies, developed by contractor medical directors, outline how contractors will review claims to ensure that they meet Medicare coverage requirements. We require that local policies be consistent with national guidance (although they can be more detailed or specific), developed with input from medical professionals (through advisory committees), and consistent with scientific evidence and clinical practice. The use of local medical review policy helps avoid situations in which claims are paid or denied without a full understanding of why. This resource-intensive process is typically reserved for high volume/high dollar items or services, and is generally conducted quarterly to facilitate orderly changes in systems. We expect to soon release guidance to the contractors designed to make development of local medical review policy

parallel our new national coverage determination process, providing more notice and opportunity for providers and the public to have input and request policies on specific matters. Copies of every contractor's local medical review policy can be found at www.lmrp.net.

We substantially improved the National Coverage Determinations (NCD) process last year to be much more open, accountable, and explicit in every respect, including the right of beneficiaries and other members of the public to request reconsideration of decisions. The new process establishes clear procedures for how national coverage policy decisions are made, allows any individual to submit a formal request for a national coverage decision or reconsideration, institutes timeliness standards and mechanisms for keeping the public informed about the status of national coverage issues, and guarantees beneficiary input through the open meetings of a new Medicare Coverage Advisory Committee. When an NCD is made, the decision is immediately posted on our web site and local contractors generally can immediately begin payment through mechanisms described above. In rare instances, when an NCD reverses an earlier national noncoverage policy and requires changes to claims processing computer systems, additional time may be necessary before payment can begin. We establish an effective date by which contractors must provide coverage. Time between an NCD and an effective date is used to establish new codes and national payment rates, make changes to claims processing computer systems, and provide explicit, written instructions on how the new policy is to be implemented. We have up to 180 days (tied to the next closest quarterly systems update) to complete systems changes from the time that instructions are generated, which can take up to an additional 60 days. However, we have completed this in less than 180 days for all NCDs under the new process, and we are continually working to further streamline this process. This 180 day time frame compares favorably to other businesses making orderly and efficient changes in electronic systems like our claims processing systems.

Within HCFA, NCDs are under the purview of the Office of Clinical Standards and Quality. Payment and coding operations are the responsibility of the Center for Health Plans and Providers. Development of local medical review policy is under the direction of the Program Integrity Group in the Office of Financial Management. Intermediary and Carrier operations are overseen by the Center for Beneficiary Services. These offices work together through the Medicare Contractor Oversight Board to coordinate coverage and payment for new technologies and to ensure clear communication of policies to the contractors.

3. I understand it can take up to two years for HCFA to change payment amounts or categories to a more appropriate reimbursement for a new technology. Apparently the first year is to evaluate a full year's worth of HCFA's internal data set—the Medicare Provider Analysis and Review (MedPAR) file and the second year, to finally implement the change.

Q: Is there any reason in this modern year why HCFA can't accept or extrapolate from partial year MedPAR data or accept statistically valid, verifiable external data form willing companies?

A: Partial year MedPAR data or external data (used in setting inpatient hospital payments) do not take into account the impact of total costs on a treatment episode, which is how care is paid for under Medicare's prospective payment systems. New technologies that in and of themselves may be more expensive than what they replace often lower total costs once fully implemented into patient care. For example, laparoscopic surgical equipment for gall bladder surgery is more expensive than the traditional surgical equipment it replaced, but it substantially reduced the number of days patients were required to remain in the hospital, and thus lowered total costs for gall bladder surgery. An accurate assessment of the total impact would not have been feasible with only limited data on costs of the equipment itself.

4. There was much discussion about HCFA's current thinking on using a "brand name" approach rather than a "category" approach for the devices and technologies eligible for the pass through in the new outpatient prospective payment system. The industry has expressed a willingness to sit down with you to work out a way to devise a category approach.

Q: Are you willing to sit down with them and Congress to devise a system which encourages competition rather than have HCFA determine the winners and losers under a brand name approach?

A: We are always willing to sit down and discuss issues with providers, Congress, and other key stakeholders, and we have been engaged in discussions about the OPD pass-through issue with device manufacturers. However, as we have explained to them, there are significant problems with the category approach they have proposed. To be eligible for a pass-through payment, the law requires that, "payment for the device, drug, or biological, as an outpatient hospital service under this part

was not being made as of December 31, 1996." As a result, many of the devices we have approved would likely not have qualified under the category approach. That is because, under a category approach, if any device in the category was being reimbursed by Medicare as of December 31, 1996, the entire category of devices would not be eligible for pass-through payments. I do not believe that this is the result Congress intended (nor a result device manufacturers would desire). Nevertheless, we have indicated many times our willingness to continue to work with device manufacturers and with the Congress to address your concerns and to provide technical assistance should Congress decide to make revisions to the statute.

5. HCFA's final rule implementing the BBA denies payment for telemedicine store and forward applications, which are widely accepted as a cost effective way to transmit an image to a remote specialist to be reviewed at a later time. Ignoring the development of this technology, HCFA arbitrarily ruled that in order to qualify as a "consultation," all practitioner/provider encounters had to occur in real time.

Q: Why is HCFA preventing the growth of this technology at a time when Congress is working to increase access to health care at all levels of society?

A: We are eager to expand the use of telemedicine and want to explore in demonstration projects the best way to do so. However, the BBA currently limits overall telemedicine coverage to consultations for which payment currently may be made under Medicare. The American Medical Association's Physicians' Current Procedure Terminology defines a consultation as an interactive patient encounter. Therefore, for telemedicine coverage under current law, the patient must be present at the time of the consultation, and a medical examination of the patient under the control of the consulting practitioner must take place via an interactive audio-video telecommunications system.

We do recognize the potential benefits that additional technologies, such as store and forward applications, can have on the delivery of health care for beneficiaries in rural areas. However, Medicare does not make a separate payment for the review of a previous medical examination. Because of the importance of this issue, we are examining in a demonstration project the effectiveness of store and forward technology as an appropriate alternative to an interactive patient encounter. We also are looking into whether store and forward technology warrants a separate and distinct payment beyond Medicare's current scope of services and what kind of legislative adjustment would be necessary to authorize such payment.

6. HCFA has interpreted that BBA telemedicine provisions to require the presence of a "presenting practitioner" in order for the encounter to qualify for telemedicine reimbursement. The presenting practitioner must be a health care provider eligible for Medicare reimbursement such as a physician, a nurse practitioner, or a physician assistant. Registered and licensed practical nurses are not permitted to serve as presenters. I think this HCFA interpretation is an unfair burden on rural areas that would like to use telemedicine to expand health care access; the HCFA interpretation artificially inflates the cost of telemedicine services.

Q: Are you planning to change this interpretation?

A: The BBA states that only physicians or practitioners described in section 1842(b)(18)(C) of the Social Security Act are permitted to provide teleconsultations. Therefore, registered nurses and other medical professionals who are not recognized as practitioners under this section of the Medicare statute are not authorized by law to receive payment for a teleconsultation. We share your concern that this may create an additional barrier to specialty services for beneficiaries in rural areas. We are currently developing recommendations on this issue, and look forward to working with you to address it.

7. HCFA has interpreted the BBA telemedicine provisions to authorize Medicare payments only for those CPT codes which include the word "consultation." This interpretation eliminates the market for many services that can be provided by telemedicine that are not consultative in nature, but rather are direct care, such as the important care provided by clinical psychologists, clinical social workers, and physical, occupational, and speech therapists.

Q: Why did HCFA interpret this provision so narrowly?

A: Clinical psychologists, clinical social workers, and physical, occupational, or speech therapists are able to receive some Medicare payments, but are not specifically listed in section 1842(b)(18)(C) of the Social Security Act as Medicare providers, and the BBA specifically limits teleconsultation payments to providers listed in that section of the Medicare statute.

CONGRESSMAN BILIRAKIS' QUESTIONS AND ANSWERS FOR THE RECORD

1. In order to provide an incentive to drug manufacturers to invest in the development of drugs for rare diseases and conditions, the Orphan Drug Act provides that

a specific product designated by the FDA as an orphan drug and approved before other designees for the same indication is entitled to seven years of market exclusivity. However, when a patient suffers from an orphan indication, it may occur that the physician, instead of prescribing the orphan drug, prescribes a competing drug (i.e. the same drug labeled for a non-orphan indication) off-label for that patient. This could erode the incentive value of the seven year orphan drug exclusivity where Medicare is a major payor for the drug (for example, with end stage renal disease).

Q1a: If a Medicare beneficiary has a condition for which an orphan drug is approved, but the patient's physician prescribes a competing drug (as defined above) off-label in place of the orphan drug, does Medicare policy permit payment for the competing drug (assuming that the drugs are otherwise covered under Medicare and that the orphan drug's seven-year period of exclusivity has not expired)?

A1a: Like any other drug, an orphan drug must be eligible for coverage under the Medicare program. Current law severely limits drug coverage; nonetheless, for the handful of drugs that are now covered, coverage for off-label use is generally determined by the Medicare contractors based on guidance in our Medicare Carriers Manuel, which states that:

> "FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."

We are not aware of restrictions in the law or regulations which would require local carriers to deviate from this standard process to account for orphan drug status. If a generic equivalent of a drug labeled for an orphan indication exists, currently, a local carrier would only need to determine if it was reasonable and necessary to cover the generic drug for the orphan condition. Or, alternatively, the local carrier would need to determine whether it was medically reasonable and necessary to cover only the trade name drug labeled for the orphan indication.

Q1b: If so, what changes (if any) could be made in Medicare claims procedures and systems to implement a prohibition against payment for such a competing drug used off-label in place of the orphan drug?

A1b: Under the current law, there is no authority for us or our contractors to exclude coverage on this basis. Our coverage criteria for an item and service, including drugs is (1) does it fall into an explicit benefit category, and (2) is it medically reasonable and necessary for the diagnosis or treatment in the specific case for which a claim is submitted.

2. Generally, under HCFA's proposal, Medicare would classify virtually all diagnostic imaging procedures based on modality. Thus, the same APC amount would be paid regardless of whether a contrast agent is used. This payment policy on its face will dissuade hospitals from utilizing contrast agents even when their use is medically appropriate. HCFA's proposal is based on the assumption that cost of the contrast agents used in conjunction with various procedures are reflected in the proposed APC amounts. However, HCFA appears to have sufficiently reliable payment data to estimate the cost and utilization of drugs and biologicals for each APC. Rather, aggregate drug data were used for calculating APC rates, resulting in APC amounts that do not adequately reflect the cost of providing contrast-enhanced procedures. Moreover, the aggregate drug data utilized by HCFA systematically excluded the cost data for the codes that hospitals were directed to use for contrast agents. The impact of these data problems were compounded by uncertainty among hospitals regarding the codes to be used for contrast agents. For example, consider low osmolar contrast agents (LOCM), which may be used in conjunction with a number of diagnostic imaging services. In July 1997, because of significant confusion among hospitals and Medicare intermediaries relating to billing and payment for LOCM in hospital settings, HCFA issued specific instructions in the Hospital Manual (Transmittal 718). However, it is clear that 1996 claims—the period that serves as the basis for APC calculations—reflect hospital billing for LOCM that was uneven and often incorrect. The exclusion of contrast agent cost data from the APC calculations has serious financial implications for hospitals that provide diagnostic imaging services and has serious patient care implications for Medicare beneficiaries who require such hospital outpatient services. Congress directed the Secretary to develop a classification system and establish groups of covered hospital outpatient department services so that services classified within each group are comparable clinically and with respect to the use of resources (BBA 4523, 42 U.S.C. 13951(t)(2)(B)). The final APCs do not properly categorize MRI and CT services and procedures into groupings that are comparable clinically and with respect to resources.

Q2a: Please explain what data HCFA collected and used to develop the APCs for MRI, CT, and ultrasound procedures, which use contrast. Specifically, was aggre-

gate drug data used and did this aggregate drug data exclude the cost data for the codes that hospitals were directed to use for contrast agents?

A2a: We used more than nine million radiology claims, matched to the radiology cost-to-charge ratios of the hospitals which submitted each claim, to determine the median costs of the radiology APCs. More than two million of the claims were for MRI, CT, and ultrasound procedures. We took great care to ensure that all related drug costs were captured regardless of where and how the hospital billed for them. For example, while our instructions call for the codes for low-osmolar contrast media to be shown in revenue center 636, which is not one that is packaged with radiology APCs, we made sure to include charges related to those codes in that revenue center in determination of the APC rates. We are confident that we have captured all drug costs related to radiology procedures, including the cost of contrast media, whether they were coded separately or as part of the procedure.

Q2b: On what basis does HCFA classify contrast agents as supplies rather than drugs? Does this determination not ignore the fact that most of these agents are approved as drugs by the FDA, that some are currently listed in the USP, and that a significant number of these agents have been approved by the pharmacy and drug therapeutics committees of many hospitals? Should HCFA consider reviewing its current treatment of contrast agents?

A2b: Our payment is not affected by the use of the word "supply" nor by the fact that the FDA, U.S.P., and formularies identify these products as drugs. Our physician fee schedule describes these media as supplies, and we merely continued using the same terminology in the development of APCs. We would capture and package the same costs whether they were called drugs or supplies.

Q2c: In light of the fact that hospitals get paid the same amount for MRI and CT and ultrasound procedures regardless of whether contrast was used, how will HCFA ensure that Medicare patients are not denied access to diagnostic imaging services utilizing contrast agents?

A2c: We do not believe that hospitals would neglect to perform medically appropriate procedures which require the use of contrast because of the outpatient prospective payment system, any more than they would neglect to perform medically appropriate procedures under the inpatient prospective payment system that has been in place and well accepted for more than 15 years.

In both settings, contrast agents are bundled with these imaging procedures and the cost of contrast material is captured in an average price. For example, payment for CT scans on average was $190 for a scan without contrast media, $236 for a scan with contrast media, and $283 for a scan without contrast followed by one with contrast and additional films. These are all captured in APC 0283, for which payment will be $237. Thus, on average, $47 has been captured to represent the cost of contrast media. Bundled payment provides an incentive to use only those resources reflected in the payment if they are medically necessary in each particular case. Over a number of cases—only some of which involve using contrast agents—a provider's costs for the contrast agent is covered.

We will, of course, closely monitor the new system as it is implemented and make adjustments as necessary to ensure appropriate payment and continued beneficiary access to quality care. But, based on extensive experience with the hospital inpatient prospective payment system, we believe that hospitals and physicians will make judicious, medically appropriate use of contrast media and other supplies. If we become aware of instances in which pressure is being brought to bear to limit appropriate use of this or any other service to Medicare beneficiaries, we will initiate medical review and take corrective action as required.

3. There are two concerns related to HCFA implementation of BBRA Section 401. (1) HCFA's suggestion that it may not permit hospitals which redesignate under section 401 to seek geographic reclassification through the Medicare Geographic Classification Review Board; and (2) the Agency's failure to implement this provision and process requests from hospitals for the redesignation permitted under the statute. The BBRA conference report accompanying Section 401 says, "Qualifying hospitals shall be eligible to apply to the Medicare Geographic Reclassification Review Board for geographic reclassifications to another area." Congress clearly defined its intent in the conference report which accompanied the bill. And the President signed the bill into law.

Q3a: Why is HCFA going against Congressional intent and the Administration?

A3a: We resolved these issues in a final regulation, which was published on August 1. We expressed concern in the proposed rule about the prospect of hospitals who were seeking rural designation under Section 401 in order to receive the benefits afforded to rural hospitals, and who might also seek reclassification through the Medicare Geographic Classification Review Board (MGCRB) back to their urban area. We do not believe that it was Congressional intent that hospitals be allowed

to game the system in this way; therefore, in the final rule, we precluded hospitals from being able to additionally seek reclassification under the MGCRB in order to receive a higher wage index or standardized amount, or both.

Q3b: How many hospitals have sought redesignation under Section 401?

A3b: Before we issued instructions to our regional offices to postpone reclassification decisions, we received notices from four facilities that were applying for reclassification to a rural area under section 401 in order to become critical access hospitals.

With regard to the implementation date, Section 401(c) clearly provides that the amendments made by this section "shall become effective on January 1, 2000." Moreover section 401(a) requires the Secretary to treat a hospital meeting the eligibility criteria as being located in a rural area, within 60 days after receipt of a request for such redesignation. MedCentral Health System of Mansfield, Ohio in Rep. Oxley's district submitted a letter to HCFA's regional office in Chicago on February 9, 2000 requesting, and demonstrating its eligibility for geographic redesignation under Section 401. The hospital received a response from the Regional Administrator on March 28, 2000 informing them that the regional office will be unable to review the request until HCFA publishes final implementing instructions. HCFA has processed at least one request for urban-to-rural redesignation, and it is my understanding that HCFA approved a request from Pawhuska Hospital in Osage County, Oklahoma.

Q3c: Why was HCFA able to take action on the Pawhuska request, but not on MedCentral Health System of Mansfield, Ohio?

A3c: We published our final rule on this subject on August 1. Our final rule provides that if a hospital submits an application by September 1, 2000, and qualifies to become rural under section 401 of the BBRA, we will deem their application to have been filed on January 1, 2000.

In the case of MedCentral Health System, the hospital is seeking both reclassification and rural referral status. Rural referral status requires a separate and distinct application process from the application for rural designation under section 401. If MedCentral is approved for rural referral status, their rural designation under Section 401 will be effective as of January 1, 2000.

Pawhuska Hospital was applying to become a critical access hospital (CAH), which makes the question of reclassification under the MGCRB moot. That is because CAHs are paid based on reasonable costs, and are not subject to the hospital inpatient and outpatient prospective payment systems (PPS). Thus, CAHs would not benefit from receiving a higher standardized rate or wage index, as would a PPS hospital, through reclassification. Additionally, Pawhuska qualified separately for rural designation under the Goldsmith Modification, which defines a hospital as rural if it is specifically located in an identified census tract. Since we determined that the specific nature of Pawhuska's situation precluded them from reclassifying under the MGCRB, we were able to process Pawhuska's application during our initial stages of implementing section 401.

Q3d: When does HCFA intend to finalize and publish a regulation?

A3d: Regulations implementing section 401 of the BBRA will be included in our interim final rule, and our specific policy regarding the interactions between section 401 and the MGCRB process are included in our final rule. The final rule was published on August 1. The interim final rule is scheduled to be published later in August.

4. A critical component of immunosuppression to prevent transplant rejection is the ability of the physician to determine, with the patient, a particular medication regimen. Switching this kind of medication without the knowledge of the physician or patient could result in a transplant rejection or even the death of the recipient. Often such substitutions are contrary to the physician's choice of treatment or prevents provision of the treatment deemed medically necessary by the physician in providing the best possible care to his or her patients.

Q: What measures or mechanisms of protection has HCFA established to overcome automatic substitution of transplant drugs, based solely on the cost of these drugs?

A: Medicare+Choice plans do sometimes limit covered drugs to those on a formulary, or list of preferred drugs, and make changes to the formulary over time. We share your concern, and on June 8, 2000 issued revised marketing guidelines about this issue. They require every plan that covers outpatient prescription drug benefits to provide notice in pre-enrollment marketing materials that it uses a formulary, that the formulary can change during the contract year, and a number to call for more information. Plans that use formularies must also disclose this fact in their Evidence of Coverage statement, which details plan benefits and restrictions, including:

- an explanation of what a formulary is and that it may change during the contract year;
- an estimate of how often the plan reviews the contents of the formulary and makes changes based upon that review;
- a description of any process by which a prescribing provider may obtain authorization for a nonformulary or non-preferred list drug to be furnished under the same terms and conditions as drugs on the formulary or preferred list; and
- a statement that members may use grievance and complaint processes if they have complaints about the formulary or its administration.

In addition, plans that use formularies must disclose whether specific drugs are on the formularies when enrollees or potential enrollees make telephone or other inquiries. The guideline is effective for contracts beginning in 2001.

5. HCFA's April 27, 1999 notice on Procedures for Making National Coverage Determinations states that HCFA will make a decision on a request for a national coverage decision within 90 days. However, it appears that this time frame applies to only a subset of coverage determinations—only those requiring the most simple of reviews or which are clear up or down decisions. HCFA states in the notice that "most national coverage issues . . . require a referral to MCAC or an outside assessment of the service." The notice goes on to set no time cap on items referred to the MCAC or for an assessment. Finally, once the MCAC makes a recommendation, the notice says it will take an additional 60 days for HCFA to either adopt the MCAC recommendation or disagree with it. After a positive coverage determination is made, the notice indicates it will then take another "180 days of the first day of the next full calendar quarter that follows the date we issue the national coverage determination" to make a payment change.

Q5b: Please provide a time line delineating both the expected minimum and maximum time frames involved for a product or procedure which goes through the entire process (i.e. HCFA, MCAC/outside technology assessment, coding, and payment processes).

A5b: The process for a national coverage determination (NCD) could take less than 90 days when evidence is clear and compelling. More complex determinations referred to MCAC or outside technology assessment bodies can take longer, depending on the amount of research and deliberation these outside experts feel is appropriate to accurately assess whether the new product or procedure in fact meets the statutory requirement of being "reasonable and necessary." Our limited experience to date suggests that the independent experts who, with industry and consumer representatives, make MCAC assessments, can take up to several months to make these determinations.

However, it is important to stress that local claims processing contractors can generally make payment for newly approved products or procedures immediately after an NCD is announced, either through an existing code that may apply or through a miscellaneous code that can be used when no existing code is appropriate. Payment amounts for claims filed under the miscellaneous code are determined by these contractors until a new code and any necessary systems changes are implemented and a national payment rate is established. In rare instances, when an NCD reverses an earlier national noncoverage policy and requires changes to claims processing computer systems, additional time may be necessary before payment can begin. We establish an effective date by which contractors must provide coverage. Time between an NCD and an effective date is used to establish new codes and national payment rates, make changes to claims processing computer systems, and provide explicit, written instructions on how the new policy is to be implemented. We have up to 180 days (tied to the next closest quarterly systems update) to complete systems changes from the time that instructions are generated, which can take up to an additional 60 days. However, we have completed this in less than 180 days for all NCDs under the new process, and we are continually working to further streamline this process. This 180 day time frame compares favorably to other businesses making orderly and efficient changes in electronic systems like our claims processing systems.

It also is important to note that the vast majority of determinations are made by our local contractors. There have only been approximately three hundred NCDs over the life of the Medicare program; 15 in the past 12 months. And we have substantially improved the NCD process to be more open, accountable, and explicit in every respect.

6. Rep. Stearns raised concerns that the notice on the new coverage process allows HCFA an additional 180 days to reimburse for a product or procedure after a favorable coverage decision.

Q6a: Is it true that in the intervening 6 to 9 months, beneficiaries will be denied access to the covered product or procedure?

A6a: Local contractors can generally begin payment immediately after a national coverage determination (NCD) is made, either through existing coding and payment mechanisms, or through generic "99" codes in each benefit category which providers can use to file claims that are then manually reviewed and priced. In rare instances, when an NCD reverses an earlier national noncoverage policy and requires changes to claims processing computer systems, additional time may be necessary before payment can begin. We establish an effective date by which contractors must provide coverage. Time between an NCD and an effective date is used to establish new codes and national payment rates, make changes to claims processing computer systems, and provide explicit, written instructions on how the new policy is to be implemented. We have up to 180 days (tied to the next closest quarterly systems update) to complete systems changes from the time that instructions are generated, which can take up to an additional 60 days. However, we have completed this in less than 180 days for all NCDs under the new process, and we are continually working to further streamline this process. This 180 day time frame compares favorably to other businesses making orderly and efficient changes in electronic systems like our claims processing systems.

Q6b: In order to assure beneficiary access to the highest quality care, please explain why the covered product or procedure could not be made immediately available and reimbursed retrospectively or why, during the coverage determination process, needed coding and reimbursement data could not be gathered?

A6b: The covered product generally can be made immediately available. As mentioned above, in rare instances, when an NCD reverses an earlier national noncoverage policy and requires changes to claims processing computer systems, additional time may be necessary before payment can begin. We have completed necessary work in such cases in less than 180 days for all NCDs under the new process, and we are continually working to further streamline this process. However, retrospective reimbursement is problematic in three ways. First, the effective dates on NCDs reflect when electronic systems will be ready to accurately process claims for the NCDs. As a general policy, we do not make retroactive adjustments for claims submitted before the effective dates of our policies, as it is not fiscally prudent. Second, it also raises questions of fairness regarding retrospective denial of payment when NCDs end coverage for items or services that had been covered. Third, this is a resource intensive process and a burden to claims processing contractors. Gathering of coding and reimbursement data requires a systematic approach to be done effectively. This also is a very resource intensive process that, given limited resources, is difficult to justify before it is known whether an NCD will be favorable.

7. This Committee worked long and hard debating, developing, and passing legislation to modernize the FDA. As a result of the legislative emphasis on collaboration, there is now much better communication and dialogue between the FDA and its stakeholders. I am aware of numerous problems with the introduction of new technologies into Medicare, including problems with the new OPD PPS. I understand numerous meetings have occurred between HCFA and representatives from the medical technology industry to try to resolve implementation problems. I applaud the Agency for their openness and willingness to meet in OPD PPS.

Q7: Yet I wonder if many of these and other problems could have been avoided by a more collaborative effort up front. I understand that the hospital industry and HCFA may meet regularly. In your view, are there any impediments to extending similar meetings to others, such as manufacturers?

A7: We have and will continue to meet with the medical technology industry to resolve implementation issues regarding the OPD PPS and other payment issues. The treatment of medical devices under OPD PPS—particularly the pass-through provisions under BBRA—have been particularly challenging for HCFA, the medical devices industry and hospitals. And it is unlikely that a new and complex payment system, such as the OPD PPS, could be developed and implemented without encountering difficulties along the way. Through continued discussions with these groups, new methods for resolving outstanding issues and implementing these provisions are evolving. We will continue to work with these groups to assure that these provisions are implemented in a manner that recognizes the competitive nature of the medical devices industry and assures access to effective new technology for Medicare beneficiaries.

CONGRESSWOMAN DEGETTE'S QUESTIONS AND ANSWERS FOR THE RECORD

1. As the Agency continues to work on this rule, beneficiaries with diabetes continue to be denied the services that would prove so valuable to them.

Q1a: When can we expect HCFA to finalize the rule it issued February 11, 1999 to implement the Medicare Outpatient Diabetes Self-management section of the BBA? Why is it taking so long for the Agency to finalize these rules?

A1a: We've been doing everything possible to publish this regulation in a timely manner. However, with the large number of regulations currently under review due to BBA mandates and other factors, the process has not moved as quickly as we would have liked. We still expect to publish the final regulation late this summer and will keep you advised on our progress.

Q1b: Also, I understand that the Interim regulation expired on June 1, 2000. What steps is HCFA taking to ensure that beneficiaries continue to receive these services?

A1b: We have focused all of our resources on publishing the final rule, which will give the greatest relief to the greatest number of people. Our operations staff have been monitoring our contractors to make sure they still honor the rights of providers to bill under the expired program memoranda. However, in response to your inquiry, we are reissuing the original program memoranda that expired June 1, 2000, to assure that beneficiaries continue to receive these services until the final rule takes effect. We will also publish new program instructions to fully implement the benefit immediately after the final rule is published to assure full compliance by contractors by the effective date of the final rule.

Q1c: HCFA has indicated a need to revise the original language in the BBA. Can HCFA provide the revised legislative language necessary to promulgate a final rule?

A1c: HCFA's Office of Legislation received a request from Representative Nethercutt's office for technical assistance in drafting this legislative change. We submitted draft language to Rep. Nethercutt's staff on July 14 and asked them to share it with Rep. DeGette and other members of the Congressional Diabetes Caucus, as appropriate. A copy of the draft language follows:

Section 1861(qq)(2) of the Social Security Act (42 U.S.C. 1395xx(qq)(2)) is amended—

(1) in subparagraph (A)—

(A) by striking "a 'certified provider'" and inserting "A 'certified provider'"; and

(B) by striking "; and" and inserting a period; and

(2) in subparagraph (B)—

(A) by striking "a physician, or such other individual" and inserting "(i) A physician, or such other individual";

(B) by inserting ", or by a program described in clause (ii)," after "recognized by an organization that represents individuals (including individuals under this title) with diabetes"; and

(C) by adding at the end the following:

"(ii) Notwithstanding any references to 'a national accreditation body' in section 1865(b), for purposes of clause (i), a program described in this clause is a program operated by a State for the purposes of accrediting diabetes self-management training programs, if the Secretary determines that such State program has established quality standards that meet or exceed the standards established by the Secretary under this section or the standards originally established by the National Diabetes Advisory Board and subsequently revised as described in clause (i).".

2. The proposed regulation for Medicare outpatient diabetes self-management would place significant barriers on community retail pharmacy participation as providers of this important benefit. For example, the rule would require these same pharmacies to employ a certified diabetes educator or nurse practitioner to provide covered benefits. Evidence suggests that quality pharmacy-based diabetes programs are operating without these additional personnel.

Q2: What steps is HCFA taking to ensure pharmacies that provide diabetes self-management services will be able to participate in this new benefit?

A2: We met with representatives of the pharmacy and pharmacist industry on March 27. They informed us that the proposed requirement to employ dietitians and certified diabetic educators or registered nurses could be a significant barrier to their qualification as certified providers, especially in rural areas. The provision regarding reassignment of benefits from the proposed rule would have required that educators be employed by a certified provider (including a pharmacist) unless the certified provider was on site supervising the educators. In response to this concern, we are considering whether to make an exception to this requirement for rural areas in the final rule.

3. The Conference Committee Report language to the FY 2000 federal budget requested that "the Administrator be prepared to testify at the fiscal year 2001 appropriations hearing on the steps that have been taken to promote access to" diabetes self management services "in a variety of settings, including those provided by State

licensed health care professionals or nationally certified nutrition or diabetes educators, as well as community retail pharmacies."

Q3: Please describe the steps that you are taking to assure that Medicare beneficiaries will have maximum access to these services in a variety of settings.

A3: As noted previously, we are drafting the final rule to expand the range of providers who will qualify for payment for the service. We've also included different ways that certified providers can meet the quality standards to better suit different settings. One example is the ability to contract with (rather than directly employ) diabetes educators in rural settings. Other examples would allow a single individual to provide the training in rural areas instead of a team, and allow the use of locations such as senior citizen centers that are approved under local fire protection and safety codes instead of limiting services to sites maintained by the certified provider. We believe these and other points of flexibility in the final regulation will address most access concerns. Further flexibility could be provided by a legislative change to allow State accredited organizations to participate (as discussed above).

CONGRESSWOMAN CUBIN'S QUESTIONS AND ANSWERS FOR THE RECORD

1. I am concerned about HCFA's Medicare reimbursement policies and how they impact rural areas of the country. The Medicare reimbursement rates for hospital services and physician services are based on certain components, and an adjustment factor is applied to each of these.

Q: What are the indexes you use to develop the geographic adjuster for hospital services and physician services, as they relate to fee-for-service, and what are the components of these indexes and how do they apply nationwide?

A: As required by law, payments to hospitals under the prospective payment system are adjusted by a wage index to reflect regional differences in the costs of labor. Hospitals are grouped into labor market areas based on whether the county in which they are located in is part of a metropolitan statistical area (MSA). A wage index is then calculated for each MSA. All of the counties of a state that are not located in a MSA are grouped into a statewide rural labor market area, and a separate wage index is calculated for those areas. The wage index is based on hospitals' labor costs as reported to HCFA by hospitals on their Medicare cost reports. The data reflect all of the labor categories employed by hospitals that are paid for under the inpatient prospective payment system (excluding physicians' patient care services). The wage index, which is updated every year, is calculated by dividing the average hourly wage across all the hospitals of a particular labor market area by the national average hourly wage. We publish the wage indices for each MSA and rural area as part of our regulation for hospital inpatient prospective payment rates.

As required by law, physician services paid under the physician fee schedule are divided into three components: 1) physician work, 2) practice expense (such as employee wages, rents, and medical equipment and supplies), and 3) malpractice insurance. On average, physician work represents 54.5 percent of the total relative value, practice expenses represent 42.3 percent, and malpractice represents 3.2 percent. Payments for a particular service vary among 89 geographic fee schedule payment areas only to the extent that the resource costs of providing such services varies. This variation is measured by geographic practice cost indices (GPCIs) which, by law, compares the local costs in each of the 89 areas to the national average for each of the three components.

CONGRESSMAN STEARNS' QUESTIONS AND ANSWERS FOR THE RECORD

1. I am troubled that the decision to remove the requirement that nurse anesthetists be supervised by a physician was made without the necessary data to substantiate that this will not put patients at risk. Please provide:

—A complete list of studies and literature reviewed by you and your staff in this regard;
—All analyses of those studies and literature that your staff may have produced summarizing or qualifying those studies;
—A copy of any report or memorandum associated with HCFA's survey of the literature;
—A copy of each of the studies and literature that assisted you in reaching your decision.

A: First, I want to put in context the overall issue of the Federal requirement for physician supervision of CRNAs and other non-physician health professionals. Congress has specified which non-physician health professionals may receive separate payment for their professional services (such as CRNAs, nurse practitioners, clinical nurse specialists and social workers). Congress left the function of licensing these health professionals to the States. Medicare recognizes the scope of practice estab-

lished by the States for these health professionals. Medicare's current hospital conditions of participation do not have Federal requirements for physicians to supervise the practice of a State-licensed health professional where there is a statutory provision authorizing direct Medicare payment for the services of that professional, with the sole exception of the current Federal requirement for physician supervision of CRNAs that we have proposed to eliminate.

The December 1997 proposed rule was developed in an effort to restructure and focus Medicare's conditions of participation for hospitals so that they focus on outcomes rather than on process-oriented requirements. We proposed eliminating many outdated Federal requirements. Unless there was compelling and sound evidence in support of an across-the-board Federal requirement for the supervision of one-State licensed health professional by another, we proposed to defer to States. We do not believe that there is such evidence to necessitate maintaining a special requirement for a single national standard of physician supervision of CRNAs in every situation. Nor is there evidence that States have been negligent in their duty to regulate health professional practice or have failed to protect the safety of their citizens through that regulation. Therefore, we proposed to change Medicare's conditions of participation to allow CRNAs to practice without physician supervision if allowed by State law, and to practice with physician supervision if required by State law.

We reviewed the literature and found three major conclusions. First, there have been significant improvements in anesthesia mortality, the anesthesia-related death rate is extremely low, and the administration of anesthesia in the United States is safe relative to surgical risk. According to the 1999 Institute of Medicine Report on medical errors, "To Err Is Human," the number of deaths from errors in administering anesthesia has dropped from two deaths per 10,000 anesthetics in the 1980s to about one death per 200,000-300,000 patients today, a 40 to 60 fold improvement.

Second, there are no studies published within the last 10 years that are specific to the issue of the final rule, namely provision of anesthesia care by CRNAs practicing without physician supervision. The studies we reviewed had significant limitations. We found no evidence that an across-the-board Federal requirement for physician supervision for CRNAs leads to better outcomes.

Third, there is no evidence that there would be adverse outcomes by relying on States and hospitals to regulate the appropriate supervision and scope of practice of health professionals administering anesthesia. Nor was there evidence that States do a poor job in their traditional domain of regulating and overseeing health care professional practice or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

We also reviewed the recently published article by Dr. Silber, et al. at the University of Pennsylvania. We do not view this article as relevant to the issue of whether Medicare should require hospitals to perform anesthesia only under the supervision of a physician, because it did not study CRNA practice with and without physician supervision. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice law, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law whereby one State-licensed physician specialty supervises the practice of another State-licensed independent practitioner. In short, there is nothing in this study that persuades us to change our decision to move forward with the final rule.

We disagree with the apparent policy conclusion of the Silber study that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs. Such a policy is much more restrictive than current Medicare policy because it would prohibit non-anesthesiologist physicians from supervising CRNAs. This would make it difficult to perform surgeries in many small and rural hospitals because anesthesiologists generally do not practice in these hospitals. The result would be that many small and rural hospitals could not participate in the Medicare program.

As part of our decision to move forward to finalize the proposed rule, we considered the feasibility of conducting a study comparing the mortality and adverse outcomes of Medicare patients for anesthesia care furnished by CRNAs with and without physician supervision. However, we concluded that it was not feasible to conduct such a retrospective study. Not only would the low overall anesthesia mortality make it difficult to develop a sufficient sample, but because of the current Medicare rules, there are no cases where CRNAs practice without supervision and thus there would be no data for the key comparison. We also considered the feasibility of conducting a study using data from non-Medicare patients. However, because Medicare's current hospital conditions of participation apply to all patients, here too there would be no data for the key comparison. Because CRNAs practice without physician supervision in certain circumstances in Department of Defense hospitals,

we considered a study using such data, but concluded that sample sizes would be too small because of low anesthesia mortality, and it would be difficult to establish appropriate comparison groups. Finally, we do not believe that it would be wise to conduct a prospective demonstration that would waive State law and prospectively randomly assign patients to study and control groups because it would remove patient choice of anesthesia professional. For these reasons, we do not believe it is feasible to conduct a study such as would be required in several bills that have been introduced.

Attached is a list of the articles (Attachment A), a review and analysis of them (Attachment B) that we considered in making our decision for the final rule, and a copy of each article (Attachment C).

ATTACHMENT A

LIST OF STUDIES REVIEWED

We reviewed the following seven studies that were published within the last 10 years and we reviewed the abstract of another study.

(1) Abenstein, J.P., & Warner, M.A. (1996). Anesthesia providers, patient outcomes, and costs. *Anesth. Analg.* 62. 1273-1283.

(2) Chassin, Mark R. Is Health Care Ready for Six Sigma Quality? *Milbank Quarterly* 764:565-591, 1998

(3) Kohn, L.T., Corrigan, J., and Donaldson, M., To Err is Human. *Institute of Medicine.* National Academy Press, Washington, DC 1999

(4) Lagasse, R.S., Steinberg, E.S., Katz, R.I., & Saubermann, A.J. (1995). Defining quality of perioperative care by statistical process control of adverse outcomes. Anesthesiology, 82, 1181-1188

(5) Silber, J.H., Williams, S,.V., Krakauer, H., & Schwartz, S. (1992). Hospital and patient characteristics associated with death after surgery: a study of adverse occurrence and failure to rescue. *Medical Care,* 30, 615-627

(6) Silber, J.H., Rosenbaum, P.R., & Ross, R.N. (1995). Comparing the contributions of groups of predictors: which outcomes vary with hospital rather than patient characteristics? *Journal of the American Statistical Association,* 90 (429): 7-18

(7) Silber, J.H., Rosenbaum, P.R., Williams, S.V., Ross, R.N., & Schwartz, J.S. (1997). The relationship between choice of outcome measure and hospital rank in general surgical procedures: implications for quality assessment. *International Journal for Quality in Health Care,* 9(3): 193-200

(8) Silber, J.H., Kennedy, S.K., Koziol, L.F., Showan, A.M., & Longnecker, D.E. (1998). Do nurse anesthetists need medical direction by anesthesiologists? *Anesthesiology*, 89: A1184)

ATTACHMENT B

REVIEW OF LITERATURE

Summary: We surveyed the literature for studies relating to the provision of anesthesia care by certified registered nurse anesthetists (CRNAs) and anesthesiologists. We reviewed seven articles that were published in the past 10 years. We also reviewed the abstract of another study. Of the seven articles, four looked at aspects of anesthesia care and one reviewed the literature on a number of aspects of anesthesia care. We also reviewed the 1999 Institute of Medicine (IOM) Report on medical errors, "To Err is Human," and a study cited in that report.

There are three major conclusions from the literature:

(1) There have been significant improvements in anesthesia mortality, the anesthesia-related death rate is extremely low, and the administration of anesthesia in the United States is safe relative to surgical risk. According to the 1999 Institute of Medicine Report on medical errors, "To Err Is Human," the number of deaths from errors in administering anesthesia has dropped from two deaths per 10,000 anesthetics in the 1980s to about one death per 200,000-300,000 patients today, a 40 to 60 fold improvement.

(2) There are no studies published within the last 10 years that are specific to the issue of the final rule, namely provision of anesthesia care by CRNAs practicing without physician supervision. None of the studies we reviewed showed a causal relationship between outcomes and type of professional who furnished anesthesia care. All the studies we reviewed had significant limitations. We found no evidence that an across-the-board Federal requirement for physician supervision for CRNAs leads to better outcomes.

(3) There is no evidence that there would be adverse outcomes by relying on States and hospitals to regulate the appropriate supervision and scope of practice of

health professionals administering anesthesia. Nor was there evidence that States do a poor job in their traditional domain of regulating and overseeing health care professional practice or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

Following is a detailed review of the studies.

Abenstein, J.P., & Warner, M.A. (1996). Anesthesia providers, patient outcomes, and costs. Anesth. Analg, 62, 1273-1283.

This paper describes a number of aspects of anesthesia care and reviews studies in several areas. The paper points out that it is difficult to attribute an adverse outcome to the three broad categories of factors that could be associated with patient death—patient disease, surgery and anesthesia—because the factors are interrelated. The paper gives the example of a patient who has heart disease and while undergoing by-pass surgery their heart becomes ischemic and they die on the operating table, despite the medical intervention. The issue here is whether the death is most attributable to the patient's underlying disease, the surgery or the anesthetic. The paper further notes that there is a problem using death as a measure of adverse outcome because the most important factor that predicts death is the severity of disease comorbidity.

The paper notes that there has been a dramatic improvement in anesthetic deaths in the last 15 years: "Since 1979, five studies have documented a remarkably abrupt decrease in anesthetic-related death rates, morbidity, and risk of perioperative deaths." The paper concludes that: "For many patients, it is now as safe to be anesthetized as to be a passenger in an automobile."

The paper notes that "identifying the cause for the improvement in anesthetic outcome is as problematic as determining the cause of perioperative death". The paper indicates that "huge numbers of surgical patients (e.g., >1,000,000) must be enrolled in studies to provide the statistical power needed to determine whether these are associations between perioperative disability or death and various anesthetic techniques, technologies, and practice models." The paper notes that studies of this size are expensive and may be ethically questionable. None of the studies reviewed for this paper meet this standard.

The paper reviewed two studies that compared mortality for anesthesia care furnished by anesthesiologists, an anesthesia care team and nurse anesthetists supervised by a physician. Both studies are flawed. Neither meets the criteria for an adequate study identified in the paper. As the authors note, the first study did not provide statistical analysis of the data. The second study used data now 25 years old and found no statistically significant difference between the groups. Neither study examined the provision of anesthesia furnished independently by CRNAs, the issue of this rule. The paper also reviewed the 1992 study by Silber et al. discussed below.

The paper suggested a number of reasons for improved anesthesia care including "new and improved patient monitoring techniques". The paper also notes that the "decline in adverse outcomes occurred at the same time that the number of American trained physicians entering and graduating from anesthesiology residency programs more than doubled (1975-1985)." The paper suggests that "the increase in the number of physicians engaged in the practice of anesthesiology is primarily responsible for the dramatic improvement in perioperative outcomes". However, the paper also notes that during roughly the same period of time, 1970-1985, the number of active nurse anesthetists doubled.

On the basis of studies which are flawed methodologically, which do not prove causality, and which do not meet the authors own criteria for rigorous study, the authors nevertheless conclude that "the presence of board-certified anesthesiologists has been associated with the decline in death and disability commonly attributed to adverse perioperative events." The author's conclusion is not substantiated by their own review and analysis of the literature. Finally, the paper presents no information regarding the issue in the rule or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

Silber, J.H., Williams, S.V., Krakauer, H. & Schwartz, S. (1992), Medical Care, 30, 615-627.

This study examined predictors of three outcomes for age 65 & older hospitalized patients for two surgeries (cholecystectomy and prostatectomy). Data were obtained on 5,972 cases in 531 hospitals in 7 states. Patient characteristics used included admission severity of illness, age, sex, and history of illnesses such as congestive heart failure, diabetes, or COPD. Hospital characteristics used were whether the hospitals

were low or high technology, number of beds, and percent of anesthesiologists who are board certified.

The outcome measures were: death rate, adverse occurrence rate, and failure rate. Death rate was defined as the ratio of the number of deaths divided by the number of patients. Adverse occurrence rate was the number of patients who developed an adverse occurrence divided by the number of patients. Failure rate was the number of deaths in those patients who developed an adverse occurrence divided by the total number of patients who developed an adverse occurrence. The following were considered adverse occurrences: cardiac arrhythmia, congestive heart failure, cardiac arrest, pneumonia, pulmonary embolus, pneumothorax, renal dysfunction, stroke, would infection, and unplanned return to surgery. Multiple logistic regression was used to determine the association between the patient and hospital characteristics and the three patient outcomes.

The study found that both hospital and patient characteristics were associated with death rates for gall bladder and prostatectomy surgery. The study found that higher death rates were associated with low technology hospitals and lower rates of board certified physicians practicing in the hospital. The study also found that patient characteristics such as age, severity of illness and history of congestive heart failure primarily were associated with adverse occurrence rates. Finally, the study found an association between failure rates and two hospital characteristics: the percent of anesthesiologists who were board certified (lower failure rates) and the presence of surgical house staff (higher failure rates).

The authors identify several limitations of the study and indicate that these limitations need to be recognized. The limitations include: there were relatively few deaths, adverse outcomes and failures, and relatively few patients per hospital so the rates could only be compared for groups of hospitals, not specific facilities. The authors indicate that their exclusion of patients admitted through the emergency department could have biased their results

In addition, the study did not address the issue of whether there is an association between the patient outcomes and the type of professional who furnished the anesthesia care. The study did not address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians, the issue in the rule. The anesthesia variable used in the study was not specific to the patient, rather it was a variable at the hospital level (i.e., percent of anesthesiologists who are board-certified). The anesthesia variable may have been a proxy indicator of quality of the hospital: thus, there would be lower mortality in the higher quality hospitals and if a complication occurred the patient would more likely be rescued. The study reports associations, not cause-effect relationships. Finally, the paper presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

Silber, J.H., Rosenbaum, P.R., & Ross, R.N. (1995). Comparing the contributions of groups of predictors: which outcomes vary with hospital rather than patient characteristics? Journal of the American Statistical Association, 90 (429): 7-18

In a subsequent article to the one summarized above, Silber and colleagues found that "most of the predictable variation in outcome rates among hospitals appears to be predicted by differing patient characteristics rather than by differing hospital characteristics, that is, by who is treated rather than by the resources available for treatment." The authors found higher proportions of board-certified anesthesiologists to be associated with lower death and failure rates, but also with higher adverse occurrence rates. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. The study did not address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians, the issue in the rule. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

Silber, J.H., Rosenbaum, P.R., Williams, S.V., Ross, R.N., & Schwartz, J.S. (1997). The relationship between choice of outcome measure and hospital rank in general surgical procedures: implications for quality assessment. International Journal for Quality in Health Care, 9(3): 193-200

Silber and his colleagues compared mortality, complication and failure-to-rescue rates. They concluded that for the general surgical procedures studied, the complication rate is poorly correlated with the death and failure rate. The authors suggest that great caution be taken when using complication rates and that they should not be used in isolation when assessing hospital quality of care. The study did not ad-

dress the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. Nor did the study address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians, the issue in the rule. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another

Silber., J.H., Kennedy, S.K., Koziol, L.F., Showan, A.M., & Longnecker, D.E. (1998). Do nurse anesthetists need medical direction by anesthesiologists? Anesthesiology, 89: A1184

This is the abstract for a study by Jeffrey Silber et al. Based on information in the abstract, the study does not appear to control for other relevant factors, such as hospital characteristics. The concluding line of the abstract indicates: "Whether this is a caregiver or hospital effect remains to be determined." This is an important shortcoming since it is not possible to conclude that anesthesiologist supervision of the care team caused better outcomes. As indicated in the above analysis of prior Silber studies, a correlation does not imply causality. It is plausible that hospital characteristics caused the better outcome and the observation in the abstract maybe incorrect.

In addition, the abstract provides no evidence that deaths and complications that occurred were associated with the competence, skill, or performance of the person who actually furnished the anesthesia. Information provided in the abstract indicates that the credentials of the person actually administering the anesthesia was not studied, but rather the credentials of the person doing the supervising was studied.

Also, it is not clear from the abstract whether like things are being compared. For example, it is not clear whether the supervision of the anesthesia team applies to anesthesiologist vs. non-anesthesiologist physician direction of a team of CRNAs (that is, medical direction of two, three or four cases concurrently) or if a single CRNA was supervised by an anesthesiologist vs. a non-anesthesiologist physician. If like things are not being compared, then it is difficult to draw scientific conclusions about an observed effect.

Moreover, the abstract does not indicate that the study compared outcomes where CRNAs were supervised and not supervised by physicians, the issue in the rule. Results cannot be inferred to CRNA performance without supervision from a study examining supervision by anesthesiologists vs. non-anesthesiologists physicians. Finally, the abstract contains no information that States are not capable of making decisions regarding requirements for supervision of one health care professional by another.

Lagasse, R.S., Steinberg, E.S., Katz, R.I., & Sauberman, A.J. (1995). Defining quality or perioperative care by statistical process control or adverse outcomes. Anesthesiology, 82. 1181-1188.

This study describes the number and type of anesthesia errors attributable to system and human factors, when the data base consists of cases that were referred to a quality assurance (QA) team. All referred cases for peer review at a university hospital in 1992 were analyzed. A total of 13,389 anesthetics were performed and the QA team reviewed 110 cases. Cases were reviewed if they met at least one of the 13 criteria recommended by Joint Commission on Accreditation of Health Care Organizations (JCAHO), at the time the study was done (e.g., cardiac arrest during or within I post procedure day). Approximately 90 percent of the errors were attributable to the system of care and approximately 10 percent were attributable to human error. System error included accidental occurrences resulting from performing a technique correctly, equipment failure (despite proper use), missed communication while following established protocol, inability to correct a disease process with current standards of care, inability to detect a disease process with current screening and monitoring standards, and inability to meet the demand for resources of equipment or personnel. Human error included failing to perform a technique properly, misuse of equipment, disregarding available data, failing to seek appropriate data and responding incorrectly to the data because of a lack of knowledge. The findings suggest that there are very few anesthesia errors but this is biased by the fact that cases were not reviewed unless a staff member reported it as a possible error. Of the cases that were reviewed very few were due to human error, such as lack of knowledge. Not only was the sample size for this study very small, but also it did not examine errors and the type of professional, or arrangement, in which anesthesia care was furnished. The study did not examine the issue of physician supervision of CRNAs.

Kohn, L.T., Corrigan, J., and Donaldson, M., To Err is Human. Institute of Medicine. National Academy Press, Washington, DC 1999

The IOM report presents a discussion on various types of medical errors, the importance of tracking and reporting on adverse events, and recommendations for effective approaches to making improvements in health care systems in order to reduce the number of errors. In a specific discussion of adverse events (Chapter 2) the report notes "anesthesia is an area in which very impressive improvements in safety have been made . . . as more and more attention has been focused on understanding the factors that contribute to error and on the design of safer systems, preventable mishaps have declined." The report goes on to note that "today . . . the anesthesia mortality rates are about one death per 200,000 to 300,000 anesthetics administered, compared with two deaths per 10,000 in the early 1980s. "The particular example of anesthesia adverse events is used to support the notion, contained throughout the IOM report, that examining all the processes involved in delivering medical care would allow hospitals to begin to make significant improvements in quality, better patient outcomes, and fewer mistakes. The report cites anesthesia care as an example where focusing on the many processes that take place during anesthesia administration creates opportunities for multiple interventions aimed at improving overall anesthesia quality. There is no specific discussion of the issue of physician supervision of CRNAs.

Chassin, Mark R. Is Health Care Ready for Six Sigma Quality? Milbank Quarterly 764: 565-591, 1998

This article, cited in the IOM report on medical errors, examines causes of quality problems and strategies for improving the quality of health care delivery systems. The author poses a challenge for the health care system to strive for the level of reduction in errors—"defect rate"—that compares to results achieved in other industries. While noting that health care barely stacks up, the one health care specialty that has reduced serious defects to rates that are close to 3.4 per million is surgical anesthesia". The author does not attribute this degree of overall anesthesia safety to any provider type or model of care but rather to ". . . a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines, and other systematic approaches to reducing errors." Adopting such practice standards and systematic approaches is fostered by the type of flexibility granted to hospitals as a result of this rule change.